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DISCUSSION PAPER

WISSENSCHAFTSZENTRUM BERLIN
FÜR SOZIALFORSCHUNG

SOCIAL SCIENCE RESEARCH
CENTER BERLIN

FS II 97-302

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ISSN 1011-9523

Forschungsschwerpunkt:
Technik — Arbeit — Umwelt

Research Area:
Technology — Work — Environment

Abteilung:
Normbildung und Umwelt

Research Unit:
Standard-setting and Environment

ZITIERWEISE ● CITATION

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Discussion Paper FS II 97 - 302
Wissenschaftszentrum Berlin für Sozialforschung 1997

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Verfahren zur Technikfolgenabschätzung des Anbaus von Kulturpflanzen mit gentechnisch erzeugter Herbizidresistenz

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SUMMARY

This report summarises a participatory technology assessment on transgenic herbicide-resistant crops organised by the Research Unit, *Standard Setting and the Environment*, at the Wissenschaftszentrum Berlin, between 1991 and 1993. The technology assessment was a ”round table” involving some fifty representatives from industry, environmental groups, regulatory agencies and science in more than ten days of controversial debate and analysis. The first part of this summary report describes the methodology used applied in analysing the deliberations of the technology assessment; the second part presents the empirical findings with respect to the performance, the risks and the benefits of transgenic herbicide-resistant crops; the third part gives an account of the ethical, legal and political discussions held in the technology assessment, as well as the recommendations for regulation advanced by the participants.

ZUSAMMENFASSUNG

Dieser Bericht ist die Zusammenfassung eines partizipativen Verfahrens zur Technikfolgen-abschätzung von Kulturpflanzen mit gentechnisch erzeugter Herbizidresistenz, das von der Abteilung ”Normbildung und Umwelt” am Wissenschaftszentrum Berlin organisiert worden war. Das Verfahren hat von 1991 bis 1993 etwa fünfzig Vertreter der Industrie, der Umweltgruppen, der zuständigen Behörden und der Wissenschaft an einem ”Runden Tisch” versammelt, an dem die Beteiligten insgesamt fast zehn Tage kontrovers miteinander diskutiert haben. Im ersten Teil dieser Zusammenfassung wird das partizipative Verfahren beschrieben und erläutert, wie aus den Diskussionen zwischen den Beteiligten Ergebnisse für die Technikfolgenabschätzung abgeleitet wurden. Der zweite Teil enthält die empirischen Befunde zu den möglichen Risiken und zum erwartbaren Nutzen transgener herbizid-resistenter Kulturpflanzen. Der dritte Teil stellt die ethischen, rechtlichen und politischen Diskussionen dar, die zwischen den Beteiligten geführt wurden; er enthält außerdem die Empfehlungen des Verfahrens zur Regulierung herbizid-resistenter Pflanzen.

Contents

FOREWORD

Between February 1991 and June 1993, a technology assessment procedure on the cultivation of crop plants with genetically engineered herbicide resistance was carried out at the Research Unit, *Standard Setting and the Environment*, in the Wissenschaftszentrum Berlin (WZB). The project was financed by the Federal Ministry for Research and Technology (No. 0319481A); it was initiated jointly by *Wolfgang van den Daele* (WZB), *Alfred Pühler* (Institute for Genetics at the University of Bielefeld) and *Herbert Sukopp* (Institute for Ecology at the Technical University of Berlin).

Crop plants with genetically engineered herbicide resistance open up new possibilities for chemical weed control. They extend the scope for application of herbicides with a wide ranging effect (nonselective herbicides), which were not practicable for most farmers up to now because they affect not only weeds but also conventional crop plants. This obstacle is removed if a gene is inserted into the plant which induces resistance to the nonselective herbicide. Herbicide resistance was one of the first projects to apply genetic engineering to agriculture. The corresponding products are now coming to the market. They are still the subject of heated public debate, concerning above all the possible risks associated with the application and release of transgenic plants and the future role of chemical weed control in agriculture.

These issues were central to the technology assessment. Taking the themes which provoked public criticism as a starting point, we commissioned a total of 18 expert reports, two commented reports and 18 commentaries on the various problem areas of herbicide resistance technology. The technology assessment was organised as a participatory, discursive procedure. It involved some 60 participants invited from scientific, business and environmental groups and from public bodies who not only provided the reports and commentaries but also discussed and evaluated them in a series of conferences. At the start of the last conference, at which the conclusions of the technology assessment were discussed and decided upon, the official representatives of the environmental groups withdrew from the procedure. These groups have not endorsed the final conclusions.

This report summarises the results of the technology assessment. It comprises three parts. The first part describes the methodology which was applied in analysing the deliberations of the technology assessment. It explains how the procedure was able to arrive at conclusions even though the debate between the participants continued to the last which seemed rather to indicate that the important issues remained a matter of controversy. We illustrate the methodology taking a strategic question from the risk controversy as an example, namely whether uncertainties with respect to the properties and behaviour of plants produced by genetic engineering can be distinguished from uncertainties due to natural processes which occur in all plants.

The second part of the summary report presents the empirical findings from the technology assessment. These findings relate to the performance and the possible impact and consequences of transgenic herbicide-resistant crops. The third part contains the discussions of the ethical, legal and political assessment of such plants; it also lists the recommendations for regulation advanced by the participants.

The expert reports delivered in the technology assessment are only available in German. They have been published, together with the commentaries and further written statements, in a series of WZB discussion papers (see Appendix below). These papers also contain a detailed overview of the range of arguments used by the participants with respect to the various problem areas of herbicide resistance technology. In accordance with the methodology described in Part I below, key areas of controversy were identified and the respective debates reconstructed as sequences of claims, objections, counter-claims, justifications, etc. This material allows the reader to follow the course and the analysis of the discussions in the technology assessment. It also makes it possible to check whether the conclusions published here give a full and fair account of the results of the procedure.

Acknowledgements. The organisation and the analysis of the technology assessment procedure involved the combined efforts of the project initiators and an interdisciplinary group from the Wissenschaftszentrum (WZB) which included *Alfons Bora* (sociology), *Rainer Döbert* (sociology), *Susanne Neubert* (agricultural science), and *Viola Siewert* (agricultural science). We also received valuable scientific help from *Inge Broer* (genetics) and *Ulrich Sukopp* (ecology). Finally, we would like to thank *Mary Kelley-Bibra*, *Christa Hartwig*, *Alex Sawyer* and *Axel Tröster-Grönig* for their technical assistance.

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Alfred Pühler
Herbert Sukopp

PART I: PARTICIPATORY TECHNOLOGY ASSESSMENT AS A POLITICAL EXPERIMENT

A technology assessment of crop plants with genetically engineered herbicide resistance was undertaken in the Federal Republic of Germany between 1991 and 1993. It was organised by an interdisciplinary group at the Wissenschafts-zentrum Berlin (WZB) (Prof. Wolfgang van den Daele) in cooperation with the Institute for Genetics of the University of Bielefeld (Prof. Alfred Pühler) and the Institute for Ecology of the Technical University of Berlin (Prof. Herbert Sukopp). This technology assessment can be considered a political experiment because various angles of embarking on new procedural courses were tried. The key words here are participation and discursivity.

The experiment fostered participation because it was based on the notion that technology assessment should be more than just a forum of experts at which the state of knowledge on the possible consequences of a technology is presented and evaluated. Technology assessment should, in addition, be a political "arena" in which the social conflicts related to the introduction of a new technology can be articulated and discussed in an exemplary manner. Consequently, participants in the procedure were put together so as to reflect all the interests and the positions of the on-going political conflicts over new technology in Germany and to include the declared advocates and critics of the specific technology under consideration. In this way, the disputes that normally take place outside the domain of technology assessment (and that often become really heated when its results are made public) were built into the procedure from the very outset.

The experiment emphasised discursivity since the whole procedure of the technology assessment was organised as a social process of on-going communication amongst those present, in order to guarantee a dialogue between the representatives of controversial positions. In a series of conferences and workshops the participants were to define the scope of studies to be carried out for the technology assessment, to evaluate the results of the expert reports that have been commissioned, and to discuss conclusions to be drawn as well as recommendations that should be given. The understanding was that such a process of on-going face-to-face communication would promote discursive forms of debate, increasing the likelihood that arguments from the two sides would be heard, and critical appraisal of the respective positions accepted.

The substantive results achieved in this technology assessment are presented in subsequent parts of this summary report. In the following we give a more detailed presentation of the organisation and the process of the technology assessment. In particular, we want to explain how results were achieved in a procedure of participatory and discursive discussion.[1]

1 Representative participation and fair allocation of resources

Which groups should be recruited into a participatory technology assessment? The organisers considered interest, political commitment and competence as the decisive selection criteria. Accordingly, at least industry and the environmental groups, as the parties of social conflict, and the regulatory authorities should be involved. Furthermore, all the problem areas of the specific technology to be investigated had to be covered by experts from the relevant disciplines. This already led to such a high number of participants that the idea was dropped of also involving politicians from all factions and the usual representatives of public life (trade unions, churches etc.). Representation of the media was offered through invitations to the press.

It cannot be taken for granted that opportunities offered for participation in a field of political conflict and controversy will readily be accepted by the parties involved. It was not difficult to assure the cooperation of scientists for the procedure, from the relevant research areas, by offering them lucrative contracts for expert reports. However, all other groups had rather mixed feelings about joining the procedure. The regulatory authorities maintained a certain

[1] More background information in van den Daele (1994). Further analysis of the technology assessment procedure is provided in Bora/Döbert (1993), van den Daele (1996, 1997), van den Daele/Döbert (1994), Döbert (1994, 1996), Gill (1993), Holzinger (1996), Neubert (1993), and Saretzki (1996).

distance by sending individuals who did not then appear as official representatives of their agencies. Both German industry and the environmental groups had fundamental political reservations. Their "coalition against participation" was certainly founded on opposing assessments of the situation. Industry was suspicious about being publicly "chastised". The environmental groups were apprehensive that their involvement would sap protest potential and would lend legitimacy to the technology investigated. In the end, however, both sides decided to participate despite their ambivalence. The organisers tried to make it clear that the procedure was open with respect to its approach and composition, and that it did not favour any side. The question is whether that convinced the environmental groups in particular. What probably also played a role in overcoming resistance to participation was that it is not easy to publicly justify refusal to participate. In addition, anyone who refuses runs the risk of watching the procedure take place without them, i.e. with the participation of the "other side" only.

BREAKDOWN OF PARTICIPANTS

Technology Assessment of Herbicide Resistant Crops

Governmental agencies	1991: 7	(1993: 10)*
Research institutions (not including institutions associated with nongovernmental organisations)	1991: 20	(1993: 25)
Nongovernmental organisations (environmental and consumer groups, representatives of organic farming, research institutions associated with nongovernmental organisations)	1991: 11	(1993: 12)
Industry and trade associations	1991:10	(1993: 13)

Figures in brackets show the distribution just prior to the final conference in 1993.

At the first conference, opposing parties criticised the composition of the participants as being imbalanced. In many cases, the calls for changes contradicted each other, for instance, both more scientists and fewer scientists were requested. Hence, there was little room for compromise. After all, there was apparently no real need for action. The divergent demands could be seen as an indication that those present represented the various positions in this controversial area. The coordinating committee (see below) prepared a proposal to solve the issue, which was submitted to the participants after the first conference for comment. No response was taken to mean tacit approval. Taking up a demand from some participants, an attempt was made to involve farmers in the technology assessment. This attempt failed, however, despite considerable efforts. A breakdown of participants in the first conference of our technology assessment, according to institutions and groups, is shown in the table above.

The number of participants in the procedure ranged from 50 to 60 persons (not including the WZB group). There were particularly high fluctuations among the representatives of environmental groups and their associations. Scientific experts were contractually bound to regular attendance. The coordinating committee supplemented the groups accordingly, without being forced to arithmetic precision, in such a way that the level of participation remained more or less constant for the various groups.

What is more significant when assessing the representativness of the composition, is the attitude of the experts to the technology under review. Of the 42 experts and commentators who participated in at least one assessment conference, a slight majority was probably in favour of transgenic herbicide-resistant crops. According to an internal rating by the WZB group, 29-48% of the participants were in favour of the technology at the beginning of the procedure, 33-43% were against it and 15-43% were neutral[2].

The technology assessment procedure constituted a major burden for all the participants—a burden which for many could not simply be tackled during their paid work. There were various kinds of problems with resources. Whereas time was probably the critical point for the participants from industry, participants from environmental groups, consumer organisations and the associated research bodies often faced financial difficulties when they were obliged to work on an honorary or self-employed basis, or were financed through donations. In the procedure, an attempt was made to compensate for

[2] The fluctuations in the rating by the WZB group did not correlate with the raters' own political preferences; they highlight the difficulty of an (external) assessment of attitudes towards herbicide resistance technology. For an evaluation of self-assessments by the participants in the procedure, cf. Bora/Döbert (1993).

this to a certain degree by ensuring that the experts from these groups were adequately considered in the commissioning of expert reports and commentaries. This was necessary in any case for reasons of equal participation. The following table gives a breakdown of the resources allocated to the various groups:

BREAKDOWN OF RESOURCES (in DM)

	Expert Reports	Commentaries	Total
Research Institutions (not including institutions associated with nongovernmental organisations)	220.000.-	5.000.-	225.000.-
Industry and trade associations	30.000.-	3.000.-	33.000.-
Nongovernmental organisations (environmental and consumer groups, representatives of organic farming, research institutions associated with nongovernmental organisations)	120.000.-	4.000.-	124.000.-
Governmental agencies	20.000.-	3.000.-	23.000.-
Total	390.000.-	15.000.-	405.000.-

What adequate consideration actually means may be a matter of argument. The fact is that in this technology assessment DM 124,000 (roughly 30%) of the expert fees went to scientists from the environmental groups or their associated research institutes. This sum does not reflect the overall volume of resources which were allocated to the critics of transgenic herbicide-resistant crops. If we include those university scientists who, according to the rating by the WZB group, were to be assigned to the group of critics at the beginning of the procedure, then this figures must be increased to DM 185,000 (45% of the total fees). The question of distribution of resources was not problematic in the procedure up to the final conference.

2 Steering of the procedure: participants, coordinating committee, WZB working group

The central steering body for the procedure of the technology assessment was a ”coordinating committee” which was set up at the first conference. In addition to the three organisers, it included three people from the side of the regulatory authorities, the environmental and consumer organisations and industry. The decisions of the coordinating committee were submitted to all participants in the procedure for final comment. Only rarely, however, were there any reactions. With few exception, the decisions by the coordinating committee were approved unanimously, which made it difficult for other participants to break out of this consensus later. As a result the participants were more informed of the decisions of the coordinating committee rather than really called upon to have a final say on them.

The participants exerted influence mainly by contributing substantive arguments to the discussions, but not by formally steering the procedure.[3] More than 40 participants were already involved in shaping the contents through the expert reports and commentaries commissioned. Moreover, all the other participants were also entitled to submit written comments, criticisms and evaluations. These were then to be discussed at the conferences and published in the technology assessment documentation. The organisers also exercised this right during the final phase of the procedure by submitting ”provisional conclusions” on the various problems, in order to focus the assessment discussion at the final conference (see below).

The WZB working group had not been formally given the remit of steering the procedure, but it did have real influence. All organisational work was undertaken by this group, from the recruiting of participants to the commissioning of expert reports to the planning of the conferences and the preparation of the assessment documentation. For a period of more than two years, an average of three persons were fully occupied with this organisational work. This extended greatly into the structuring of the contents of the discussions on the procedure. In formal terms, the WZB working group acted as the planning staff who continued to be dependent on the coordinating committee and who prepared and executed the latter’s decisions. But this cannot conceal the fact that an ”apparatus” of this kind

[3] Only at the first conference did procedural matters play a central role but it was not possible to find a binding solution at that time. It is just not feasible for some 50 to 60 persons with, in some cases, diametrically opposed interests to jointly conduct a technology assessment procedure on the basis of self-organisation—at least not within an acceptable period of time.

can exert considerable influence. A certain degree of internal control was ensured by the fact that the WZB group itself had been put together to reflect the various disciplines and political orientations pertinent to the controversial technology.

All strategic decisions in the course of the technology assessment procedure were taken unanimously in the coordinating committee. This was the case for

- the composition of the participants,
- selecting the subjects for the expert reports, and the subsequent commissioning of the reports and the comments requested thereon,
- the form of publication of the materials and the results of the technology assessment, including the depiction of the various positions of the participants and consideration of these positions in the final synthesis report by the organisers,
- the sequence of colloquia and assessment conferences,
- the way in which preliminary results of the technology assessment should be presented for discussion among the participants in the final conference.

In the coordinating committee (contrary to the situation in the plenary assembly of the participants) conflicts were settled through negotiation. All members of the coordinating committee had a factual right of veto. The remit for the steering of the procedure was subject to the condition that the decisions at the "round table" had to be taken jointly. This did not exclude situations in which people occasionally let themselves be outvoted.

3 Selection of the subjects for the expert reports

The selection of the subjects for the expert reports to be prepared in the technology assessment and of the individuals from whom the reports should be commissioned were dealt with at the first conference. To this end, the WZB working group proposed a provisional programme structure which was the result of numerous discussions with potential experts conducted over a period of several months. The declared goal was to cover, if possible, all the problems associated with transgenic herbicide-resistant crops raised in the scientific literature and the public debate. The experts we considered were invited to present an outline of their reports for discussion at the first conference.

The programme proposal was criticised from various sides. On the one hand, the broad range of topics was criticised, that often did not reveal a specific link to transgenic herbicide-resistant crops. This argument was raised in particular against plans to have the problems of nonselective herbicides examined in detail. On the other hand, the spectrum of subjects was criticised as being too narrow. Additional reports were solicited by the representatives of nongovernmental organisations: for instance, on soil erosion, on the patenting of genetic resources from the Third World by companies from the industrialised countries, and on the power and interests of the groups involved in the technology assessment, with special reference to a comparison of industry and the environmental organisations.

Final agreement on the programme structure was not reached during the first conference. The question was delegated to the coordinating committee which took two meetings to draw up a final programme proposal. The proposal was presented in written form to all participants for comments and was then taken as accepted as no further objections were raised.

The final programme structure contained two decisions concerning the strategy of the technology assessment. First, it adopted a technology-induced approach; second, it rejected proposals to have expert reports on political issues, such as the power structure of the conflict over new technology, or the interests and objectives of major actors in that conflict, because such questions have a strong normative touch and can only be dealt with empirically to a limited degree. It was decided that an expert report on ethical issues be commissioned, but that was expressly limited to the moral questions of plant manipulation. A proposal to commission a comprehensive ethical report to assess all the value judgements brought forward in the technology assessment was also rejected. In general, these programme decisions reflected the understanding that value judgements cannot and should not be relegated to experts. Moral and political evaluation is the proper domain of lay citizens. This means that in our technology assessment the competence for value judgements rested with all the participants as a group. While these decisions appeared adequate, in principle, they added to the underestimation of normative and political issues in our technology assessment; they ruled out that these issues be put automatically on the agenda through the critical discussion of the respective expert reports.

4 The approach: technology-induced versus problem-induced assessment

Two criteria were applied by the organisers in drafting a preliminary list of the substantive issues to be investigated in the technology assessment: (1) all the arguments advanced in public for and against transgenic herbicide-resistant crops must to be dealt with in the technology assessment; (2) the technology assessment should address the possible consequences of herbicide-resistant crops, not the possible options for weed control in agriculture.

While it would have been difficult not to agree with the first of these criterion, the second evoked considerable criticism from the side of the nongovernmental organisations in the first conference of the procedure. These participants had fundamental reservations about the narrow approach of the technology assessment which was "technology-induced". This approach takes the emergent technological option of transgenic herbicide-resistant crops as the starting point; it focuses on the analysis of possible consequences of such crops and on the political actions that might be necessary to cope with those consequences. What the nongovernmental groups called for instead was "a problem-induced" technology assessment. This approach addresses the underlying problem the technology is supposed to solve and compares alternative options for tackling that problem. In the case of herbicide resistance, the starting point would then have to be the agricultural problem of weed control and a comparison made of the options offered, on the one hand, by industrialised, intensive farming and, on the other, by organic farming. The decisive questions would then have been whether we really need transgenic herbicide-resistant crops and whether they fit into a system of agriculture that is socially desirable and ecologically sustainable.

A "problem-induced" technology assessment allows the discussion of broad and fundamental political issues, but, at the same time, it inflates the scope of technology assessment to issues of political planning in the broadest sense and to scenarios of desirable futures for social development. While this may be a necessary input into the public debate, it cannot be a reason to forego the more modest efforts of a technology-induced assessment. In fact, had the participants of our procedure come out in favour of a comparative analysis of weed control techniques that fit alternative systems of agriculture (intensive versus organic farming) none of the issues raised in the technology-induced assessment of transgenic herbicide-resistant crops would have been invalid. Rather, additional and corresponding questions would have had to be addressed for organic farming as well. The programme of the technology assessment would then have been doubled at least.[4]

The dispute about the proper approach in technology assessment is as old as technology assessment itself. The more such assessments were seen as a vehicle to revise in principle the dependence of modern societies on technological dynamism, the broader became the horizon of problems to be considered. Thus technology assessments have regularly proceeded from the analysis of the consequences to the analysis of the origins of the technology in question, moving from control to design and from technical options to social needs. Equally regularly, however, political and pragmatic constraints imposed a return to more conventional types of assessment which focus on the control of the consequences of new technology. Perhaps the optimum would be to pursue the different approaches in parallel or in cooperation. However, most of the studies which bear the title of technology assessment apply the technology-induced approach.

In the end, this approach was adopted in our technology assessment, with a minor modification: In order to guarantee that the perspectives of broader technological and agricultural alternatives were represented in the procedure, a special expert report on weed control in organic farming was commissioned. The environmental groups (temporarily) accepted this arrangement. The working programme of the technology assessment was approved in consensus and ceased to be a subject of dispute until directly prior to the final conference.

5 Issues considered: risks, benefits, and alternatives to transgenic herbicide-resistant crops

In the working programme that was determined for the technology assessment, the possible risks of transgenic herbicide-resistant crops became the central theme. Discussion of the possible

[4] The evidence, too, that a problem can be solved with conventional, technological resources does not mean that it is no longer necessary to examine new technologies. A new technology could bring with it a major improvement. Studies of alternatives place symmetric demands on new and old technologies—unless there are reasons why new technologies would, in principle, be less favourable than old ones.

benefits was of far less importance and the alternatives to herbicide-resistant crops played only a limited role.

Of the twenty expert reports commissioned for the procedure, six dealt more or less exclusively with the risks of genetically modified plants; seven dealt with the toxicological and ecological risks of nonselective herbicides which will be applied in conjunction with the resistant crops. The expert report of the Öko-Institut Freiburg constituted a kind of reference report summarising all the relevant risk arguments. The other expert reports were related either directly as commentary reports or indirectly by way of parallel questions to that report. The paramount issues that emerged from the discussion were whether the risks of transgenic plants differed from the risks of new plants that have been altered through conventional breeding techniques, and how the hypothesis that there are special risks for genetically modified plants could possibly be justified.

The predominance of the risk aspect in the technology assessment procedure had a whole series of consequences: First, it turned the technology assessment into a kind of prior examination of all the issues which had to be tested in any case for the approval of transgenic herbicide-resistant plants and nonselective herbicides. Sometimes it was difficult to comprehend why the problems had to be settled in a technology assessment and could not be left to the competent authorities. This applied more to the potential risks of nonselective herbicides than to the risks of transgenic plants because, for the latter, tests and procedures for approval appeared to be less well-established. Second, issues of judgement and valuation were given less emphasis than empirical aspects. In most cases the factual preconditions of risk claims were controversial, i.e. the causalities, the probability and the scale of potential damage. The normative reference points of risk assessments, by contrast, were often uncontroversial: When toxic plant ingredients develop, approval will be denied. Third, the technology assessment implicitly accepted the fact that new technology is evolving in a social process that largely evades political control as the starting point. The hidden premise of all risk discussions is a distribution of the burden of proof which favours innovation: Special justification is required if a new technology is to be restricted or banned, not if it is to be invented or propagated. In line with this rule, many of the discussions in the technology assessment followed a pattern in which the critics had to make claims of risk and, when faced with objections, were forced to substantiate these claims with further argument.

The preoccupation with risks can probably not be avoided in any technology assessment. In a society in which technical innovation is built into the structure of science and industry, and anchored in the constitution by a guarantee of individual rights, opposition to innovation is bound to resort to risk arguments. Not surprisingly, therefore, the main criticisms of genetic engineering in public speak the language of risk. And, as long as this is the case, risks must also be the main subject of a technology assessment. It would seem to be a minimum requirement of any technology assessment that it examine the legitimacy of the concerns and arguments which the people raise in public debates.

Benefit analyses in our technology assessment procedure concentrated on the claims of the advocates of transgenic herbicide-resistant crops that nonselective herbicides implied clear ecological and agronomic advantages. Here, different assessment frameworks were taken as the basis. On the one hand, even small ecological and economic improvements were chalked up as progress vis-à-vis the status quo. On the other hand, it was criticised that the improvements claimed did nothing to alter the fundamental problems of intensive farming; they were simply variations of a trend which had to be seen as mistaken development and did not, therefore, constitute real benefit.

In claims of benefit, the advocates of a technology have the burden of proof. However, according to the legal principles that apply in most industrialised countries, this does not establish any symmetry to the burden of proof required of the critics with respect to the risks of the technology. If critics fail to provide evidence of relevant risk, the technology cannot be banned. If the advocates fail to provide evidence of relevant benefits, the technology still cannot be banned. At best, public support of the technology can be withdrawn. What ”society” needs is normally decided on the markets. It is not the subject of political regulation. In our technology assessment, reference to this regulatory structure took the sting out of the debate over whether we actually need transgenic herbicide-resistant crops. There was, however, no necessity to abide by the limits of existing law, since it is within the scope of a technology assessment to investigate more issues than can be politically regulated. Whether there is an acceptable demand for herbicide-resistant crops is a legitimate question, even when the answer can only have an impact on public awareness and level of consciousness, and may not, in itself, constitute sufficient reason to impose legal restrictions on the technology. Furthermore, it is also a legitimate matter for discussion whether socioeconomic need could be made a precondition for the approval of a new technology, even if that would imply a revision of constitutional law.

Within the framework of our technology assessment fundamental questions of this kind were scarcely touched upon (but see section III, D below). Probably, because of the otherwise missing regulatory relevance, questions of need were mostly referred back to discussions of risk. The thrust of the argument was that uncertainties about risks that might be hidden in a new technology should not be offloaded onto society unless there is a real need for that technology.

Discussions of alternatives to transgenic herbicide-resistant crops were largely confined to the level of technical details. Comparison with the potential and problems of mechanical weed control was repeatedly brought forward, but even then the established system of intensive agriculture was taken as the frame of reference. Organic farming was covered in an expert report on nonchemical methods of weed control; it was not, however, a subject-matter for investigation in the technology assessment.

6 Reference to scientific knowledge and the role of experts

The final stage in every technology assessment is a political evaluation of the technology under consideration; the main strategy is, however, scientific investigation. Evaluations are based on reasons which have empirical references, that is, they refer to statements on causal mechanisms, facts and phenomena which are (at least in principle) verifiable or refutable. Whether unintended metabolic changes justify a ban on transgenic plants or whether increases in yield through the use of herbicides are useful, is a value judgement. Whether metabolic changes do occur and whether increases in yield can be expected is something one can investigate and know. And even if we determine that we do not or cannot know it, we still refer to the domain of knowledge; establishing the limits to knowledge is a matter of knowledge.

The commitment to knowledge and information inherent in the notion of technology assessment seems to be the basis for the broad political consensus which supports that notion in our society. Were political interests the only aspect that really mattered, then technology assessment would be a waste of both time and money. The interests are, in general, known in advance. The important point is that the interests participants pursue when they enter a technology assessment procedure must be sifted through the filter of information orientation and, so to speak, expose themselves to the risk of information. The very idea behind technology assessment is that it involves the possibility that handy claims, by means of which one can beat the drum for a technology in public or provoke resistance to it, can be shown to be unprovable, poorly justified or simply wrong. This does not mean that political interests or goals can themselves be ”refuted”, but they can lose their favourite legitimation. To justify them, new reasons must then be provided. This risk can only be circumvented by circumventing technology assessment altogether; once you participate, you are automatically exposed.

Commitment to information imposes limits on the function of the technology assessment procedure to provide a forum for the political conflict over technology. Despite this, or perhaps because of it (depending on the political stance adopted), this commitment was accepted as the working basis by all those involved in our procedure. The Gene-Ethical Network (a leading group of activists campaigning against genetic engineering) declined to participate precisely because the procedure seemed incompatible with the straightforward goal of political mobilisation of the general public. This abstention was declared to be a matter of political ”division of labour” among the critics of the technology. It was not (at that time) considered a fundamental rejection of the technology assessment. It is very possible that the ”virtualisation” of political aspects through the information orientation of the technology assessment was only reluctantly accepted and viewed as a concession by the social movements. For industry and many scientists it was an essential precondition for their participation; they would have declined to ”just talk politics”. Compromise was necessary. Within the framework of a voluntary procedure of technology assessment, the conditions for participation must be symmetrical. Unequal distribution of power and resources in the society must not affect the position in the procedure. Fair and equal treatment must be guaranteed. On the other hand, symmetrical participation also means, that oppositional groups cannot expect that the disadvantages they face in politics in general will be compensated for by preferential treatment in the technology assessment.

There was consensus in our procedure that expert reports were to be a main element in the technology assessment. However, there was also general agreement that the expert reports should not be its only result. They were to provide the basis for the political evaluation of transgenic herbicide-resistant crops. Furthermore, it was agreed that issues of information were first and foremost the competence and responsibility of the experts from the relevant scientific and technical disciplines. The very fundamental political criticism sometimes waged against expert knowledge and expert cultures, both in the social movements and in the social sciences during the last 20 years, did not have any role in our procedure.[5]

Perhaps the competence and responsibility of the experts were less contested in our technology assessment because greater transparency was guaranteed here than in other contexts of scientific advice for public policy. The role of the experts was modestly defined, and exaggerated claims or "technocratic arrogance" were effectively excluded. It was clear from the beginning, therefore, that the knowledge of experts is inherently limited. Every expert report had the explicit task of presenting what was known about a specific problem, what could be known, and what was not known. The bringing together of experts with different political convictions guaranteed that the unavoidable "softness" of expert opinions became a matter of discussion, and that scientific controversies, where they existed, would be brought to light. The participants in the technology assessment agreed that forecasts on the basis of theory are never absolutely certain, that the examination of empirical claims depends on the methods adopted, and that science can only depict complex realities in a limited manner.

It was equally clear in the procedure that experts are not truly "disinterested"; they do indeed have interests and make value judgements. The experts were even asked explicitly (although in most cases in vain) to make clear value judgements at the end of their reports, to trigger political discussion. Within such a setting, it was not very cogent to propagate the notion that experts are politically "neutral". This did not mean that the reverse conclusion was drawn that experts were merely the representatives of interests. The participants in the procedure, as a group, were able to distance themselves from the value judgements of the experts, to differentiate between facts and evaluations, and to establish what the experts knew and what they wanted in political terms or thought was right.

Thus, the politicisation of the experts in the technology assessment was within bounds. Legitimate room for political judgement was provided in the selection of the questions to be addressed in the expert reports and in the evaluation of the findings. The findings, themselves, were supposed to be science not politics. They were a matter of knowledge, not of interest.

7 Assessment conferences: science-based discussions

For the evaluation of the expert reports prepared in the technology assessment, discussion among participants was the decisive "arena". Discussions were held at two (two-day) conferences which had been prepared in three (one-day) colloquia. All participants had previously received the expert reports and a short five-page summary. In order to guarantee the active involvement of as many participants as possible and to foster controversial discussion, commentaries were commissioned for each report from participants of the "other side". The commentaries were supposed to point out:

- whether the central findings of the report were substantiated,
- whether important aspects were not covered,
- whether the report was based on implicit or unusual premises,
- whether the conclusions were plausible.

The members of the coordinating committee took turns acting as moderator at the conferences. They were not responsible for summarising the findings of the discussions, but rather, ensuring that no points or contributions were omitted. It was their task, from time to time, to pool the arguments in order to structure discussion. The WZB working group was to support the coordinating committee in this respect. Discussions at these conferences presumably suffered less than is normally the case from time pressure; but they had other characteristics which were also constraining: the discourse was scientific rather than political; it was process rather than result-oriented.

The relative "reticence" of participants with respect to normative and political questions could perhaps be attributed to a certain preadjustment to the timetable of the technology assessment, which assigned the complete last conference to the discussion of these questions. On the other hand, it had never been the intention to postpone political questions to the last conference. It was far more the case that the coordinating committee had expressly indicated that the expert reports and commentaries should contain conclusions based on value judgements, which should be seen as the starting point for political discussions. This was only done to a

[5] See van den Daele (1996).

very limited degree, however. With the exception of the expert report on the ethics of plant manipulation, which was explicitly oriented towards value judgements, all the other expert reports and commentaries confined themselves to empirical, scientific arguments. One explanation could be the commitment to ”neutrality” associated with the role of expert. What probably had more of an influence was the fact that the participants, themselves, defined their controversies mostly as debates about empirical findings and not about values and goals. What was to be classified as damage was less a subject of controversy than whether the damage could possibly occur and how likely it was.

No one argued that the problems dealt with in the technology assessment were not empirical but political in nature, and that everything depends on what you want or find acceptable. With this argument the whole debate over the alleged special risks of transgenic herbicide-resistant crops would have been beside the point. Participants adhered to the relevance of empirical questions for various reasons. First of all, they agreed on many normative questions which meant that there was little room and little need to introduce completely new arguments with respect to valuation. Furthermore, the political force of nonconformist normative arguments is probably rather limited, because they may be relegated to the sphere of pluralism or outvoted by majority decisions. As a strategy of political critique, therefore, it is often more effective to attack factual claims that are based on agreed valuations than to call for alternative values. In any case, at the assessment conferences lengthy normative and political discussions were the exception.

The discussions worked through central claims in the expert reports, i.e. they called for substantiation and proof, raised objections, formulated and examined counter-arguments. Although the arguments went back and forth or in circles (in line with the sequence of requests to take the floor), they often accumulated as far as contents were concerned. However, this accumulation rarely led to a declared convergence of positions or to settlement of dispute. In individual cases, arguments were explicitly withdrawn and replaced by arguments on a different level. Sometimes there was a call for the assembly to record the result of discussions as a declared consensus or dissent. This call was not followed by most participants. In addition, the moderators intimated that it would not be possible to summarise *ad hoc*, in a reliable manner, the non-transparent state of discussion. The dynamics of the assessment conferences were, therefore, process rather than result-oriented. In a way, the discussions were deliberations without conclusions or, in legal language: the taking of evidence without a final decision. How can one then derive conclusions from such a procedure? The final conference was designed to solve this task.

8 The use of argumentation: How conclusions were derived through discourse

The final conference of the procedure had two functions. It was to bring to the fore the political problems of transgenic herbicide-resistant crops which had not been discussed extensively up to then. And it was designed to do what the assessment conferences on the expert reports had not done, namely, to draw conclusions about the empirical findings from the deliberations among the participants.

Political problems relate to the question, ”What should be done?” For instance, should transgenic herbicide-resistant crops be approved or banned? Are the risks of genetic engineering acceptable? Should new technology be regulated stricter than old technology? Throughout the technology assessment all participants proceeded from the premise that political questions were to be distinguished from empirical questions, and that the finding of facts must be prior to the moral and political evaluation—both in time and in logical order. Before we ask whether a risk is acceptable we have to ask whether the risk exists. It may, of course, be the case that no answer can be given because the requisite knowledge is lacking or the matter is controversial. But this, too, would then be part of fact finding (or evidence taking), and it must also be recorded before political judgement can refer to it.

But how can empirical results be recorded in a participatory procedure, when the participants merely discuss an issue without determining whether consensus has been reached or not? After all, our technology assessment was set up as a discursive procedure with no third instance, that is, no one who acts as judge and who, after listening to the evidence from all parties present, is competent to take a final decision. In such a discourse it is up to the participants themselves to judge.

The WZB working group which was assigned the task of preparing the final conference proposed a methodology for summarising the empirical findings of the technology assessment. The methodology was approved by the coordinating committee. It involved three steps:

- giving an overview of all the arguments presented by the participants with respect to the issues of debate,

- reconstructing the state of argumentation reached in the debates which were particularly controversial,
- formulating ”proposed conclusions” which were then to be considered and decided upon by the participants.

There were arguments in the working group about this methodology. It was generally agreed that first of all an overview should be presented of all the arguments advanced in the procedure (in the expert reports, in the commentaries and discussions). To this end, argument trees were developed for the various questions that had been discussed, in which statements for and against were put together visually in a kind of synopsis. What was controversial was whether the next step should be taken and the arguments classified according to content, i.e. whether they should be reconstructed as a sequence of claims, counter-claims, substantiation, objections, counter-objections, etc. It was criticised that a reconstruction of this kind could be biased by value judgements from the side of the working group, and that it could put the statements of the participants into contexts which they may not have intended. Against this criticism it was pointed out that such a reconstruction was necessary to truly reflect the course of the procedure. The undifferentiated block apposition of arguments pro and con would merely stress the divergent nature of the positions. The participants had, however, also produced convergence between these positions.

In fact, the participants did not merely express opinions. They continuously argued with one another (i.e. against each other). The procedure prompted discursive communication, that is, in the actual dialogue, substantiation of claims was requested and provided, objections raised and countered, evidence offered and examined. Hence, the communication between the participants differed greatly from the usual ”public discourse”, which seldom moves beyond the repeated announcement of positions. When people engage in real discursive deliberations they cannot but open their positions to debate. In a true discourse, the participants do not have complete control over their arguments. The arguments have a life of their own; they may run contrary to the intentions of those who state them. What results after discourse as ”the state of argumentation” can be far more than the simple collection of all the statements the participants have put on the agenda. It was reasonable, therefore, that in a participatory technology assessment an attempt should be made to identify such results—if there are any.

For that reason the WZB working group decided to reconstruct the arguments in the procedure into controversial strategic positions and to add this reconstruction to the documentation for the final conference (see next paragraph for an example). Whether the working group did this in an arbitrary manner was something which had to be examined by the participants. They were explicitly invited by the coordinating committee to exert such control:

> ”The reconstruction of arguments orders the statements of the participants with reference to the contents; it does not reflect the actual order in time (in what sequence they were said) or in place (where they were said in reports, commentaries or discussions). The reconstructions explicate the state of argumentation which was achieved in the discourse with respect to controversial issues. They represent the taking of evidence, in which the participants had been engaged. Whether they really provide evidence, that is, whether the state of argumentation the participants have produced, is complete and conclusive, is another question. Any participant may, at any time, point out that relevant arguments are missing or that the objections and counter-objections reconstructed here are unproved or false.
>
> The reconstructions are nevertheless useful. With them it is no longer possible just to disagree without stating to which point exactly it is that one objects and without giving further reasons for the objection. This procedure ensures that there is progress in the discussion, even if controversies remain unresolved. It becomes clear where and why disagreement exists. Hence external observers of the technology assessment would be in a better position to evaluate the discussions and draw their own conclusions.” (Circular letter no. 13, May 3, 1993)[6]

Even when all the arguments have been summarised and ordered, there are still no conclusions as to the results. The state of argumentation does not formulate the results. However, it does make the step to formulation of the results transparent and comprehensible. This step is not a logical derivation which could be left to the computer. It is an act of cognitive evaluation which must weigh the arguments advanced against one another. Different evaluations may be possible, but these are in any case subject to two conditions: (1) no new arguments may be

[6] Reprinted in van den Daele (1994: 49).

added; (2) no assessment should be made of whether something is politically desirable or defensible but only, in the words of Ludwig Wittgenstein, whether it actually is the case. Has the claim been proven? Has the objection been refuted? Is the hypothesis substantiated? Is this a scientific controversy? The conclusions are cognitive evaluations, not political or moral ones.

Conclusions of these kinds were formulated by the organisers of the technology assessment and presented to the participants in the final conference. This was in line with a decision by the coordinating committee that the organisers present a draft of the final report on the technology assessment, that they intended to deliver. The proposed conclusions were presented as provisional; the participants had the right to declare consensus or dissent.

> ”It seems necessary to make precise proposals for how the results of the technology assessment should be formulated, regarding the controversial issues surrounding transgenic herbicide-resistant crops. In view of such proposals consensus or dissent will also be precise and remaining conflicts can be better understood. It would be highly unsatisfactory merely to convey as a result that opinions continue to be divided over all major points of debate. In this case, the whole participatory procedure could have been spared, because that was known before.
>
> A crucial question is, of course, which conclusions should be presented to the participants to solicit their assent or dissent. The answer can only be: the most plausible ones, given the state of argumentation in the procedure. While such conclusions cannot be derived with pure logic, they are also not arbitrary or merely a matter of subjective feelings. The organisers claim that the conclusions they propose have been suggested by the arguments which have been advanced. These conclusions are more plausible than others. This is why the organisers think that the final conference should discuss and examine these conclusions rather than others.” (Circular letter no. 13, May 3, 1993)

This methodology put the participants under great pressure either to admit consensus or justify dissent. This was criticised. However, pressure for consensus was only exerted with respect to the empirical aspects of the problems related to transgenic herbicide-resistant crops. The very notion of a technology assessment is based on the premise that judgements on empirical issues are neither arbitrary nor merely matters of interest. Otherwise attempts to take evidence on these issues by consulting experts would be beside the point from the outset and, consequently, one would also have to desist from claiming that arguments presented in the public debate are substantiated by scientific knowledge.

Pressure for consensus does not mean that at all costs there must be a result and that this must be accepted without opposition. It means that the result can only be rejected with a growing burden of substantiation. One can no longer simply point out that one is of a different opinion. Goals may be simply rejected, because they are a matter of choice; but not empirical findings—they are (at least in principle) a matter of knowledge. The true domain of irresolvable dissent is politics, not science. And, with respect to the political evaluation of transgenic herbicide-resistant crops, it was indeed the intention not to press for consensus in the final conference, but rather to provide open opportunity for diverging judgements.

9 Example: Conclusions concerning specific risks of genetically engineered plants

The question whether there are specific risks involved in transgenic plants, that do not occur in plants modified by conventional breeding techniques, was a central issue in our technology assessment.[7] The report by the Öko-Institut argued that there was at least an increased probability of unexpected side-effects with transgenic plants. One reason for this was that the insertion of transgenes would disturb the genomic context of the host plant and induce positional effects (insertional mutations). The counter-argument was that insertional mutations also occur when transposable elements (jumping genes) which are naturally contained in plant cells move around; therefore, disturbances of the genomic context could not be considered as a risks that is in any way specific to transgenic plants. The Öko-Institut defended its position by claiming that transgenes and transposons cannot be compared. This point prompted a lengthy discussion in one of the assessment conferences. The arguments were summarised for the participants in the following reconstruction:[8]

[7] The final conclusions with respect to this issue are presented in, section II A5

[8] For a full documentation of this controversy see the material in (Weber 1994: 215); see also van den Daele (1996).

Controversial issue (claim by the Öko-Institut):

Transgenes induce disturbances of the genomic context which are different from those induced by the insertion of transposable elements which are endogenous in the plant. Therefore gene transfer cannot be compared with changes in the plant genome which occur naturally.

Arguments:

1. That context relations in the host genome are disrupted is nothing which is specific to genetic engineering. The transfer of genes is, in this respect, comparable to the insertion of mobile DNA sequences (transposons). Such insertion, too, separates neighbouring genes.

2. Transgenes and transposons may be comparable as far as the disruption of the sequence of genes is concerned. They are, however, significantly different in other respects.

Transposition is a rare event; transgenic plants are frequent.

3. Natural changes of the genomic context through the insertion of transposons will seldom give rise to new plants, whereas transgenic crops will be grown in large quantities.

4. Transgenic crops must be compared with other crops, not with wild plants. Transposons play an important role in breeding corn. The resulting cultivars (sweet maize, for example) are grown in equally large quantities. There is no difference here to transgenes.

Transposons do not transfer dominant genes.

5. In contrast to transgenes, transposons cannot transfer dominant genes which will be expressed; they can only switch off existing, recessive genes.

6. Transposons also transfer an active gene (coding for transposase). In addition they contain regulatory sequences which can activate silent genes. This also leads to the formation of a new protein in the plant.

7. New plant properties may be possible through transposition, but dominant genes cannot be transferred. This remains a difference.

8. The point is whether this makes a difference with respect to possible changes in the genomic context. In this respect, the effects of jumping transposons and the integration of transgenes are comparable.

9. Transposons do not transmit genetic information that is new to the plant. Transposase is not an "alien" gene product; it is already known in the plant.

10. The fact that genetic information is "alien" to the plant may be relevant for the possible consequences of the gene product (coded by the gene). It has no relevance, however, for the question of how the genomic context will be changed by the integration of the gene.

11. It is conceivable that new information could also make a difference with respect to the genomic context.

Integration of transposons is regulated by the plant; transgenes insert at random.

12. The integration of transgenes cannot be controlled. It is random. There is no fitting site for transgenes in the host genome. In contrast, transposons jump (at least in part) to specific sequences.

13. The current state of knowledge is that transposons are inserted at random. They move through the genome in a stochastic process without preferring certain sequences or chromosomes.

14. Earlier studies (Saedler *et al.*) have found homologies between transposons and sequences at the site of integration. It was suggested that this indicates that integration is sequence-specific.

15. This hypotheses was withdrawn by the authors. It could never be shown that transposons use homologous sequences for integration. The homologies occur by chance—which is to be expected according to statistical rules.

16. The thesis withdrawn is still upheld in other work (e.g. Fedoroff, 1991) as representing the state of knowledge in science.

17. Fedoroff (1991) only refers to the regulation of the frequencies of transposition.

18. Transposons are switched on and off according to regulation by the developmental cycle of the plant. For instance, it has been demonstrated that the frequency of transpositions in maize depends on the stage of growth of the plant.

19. With respect to the possible changes in the genomic context, the relevant question is whether the site of insertion is regulated, not the frequency of insertion. There are no indications, however, that the site at which transposons are inserted is in any way regulated by the plant.

20. The frequency of changes induced in the genomic context (activation and deactivation of other genes) is also regulated by the development of the plant. This does not apply to transgenes.

21. If this applies, it can only relate to the time of the context changes not, to the type and the consequences. The consequences of changes in the genomic context because of the insertion of a transposon cannot differ from the consequences of the integration of a transgene (at the same gene locus).

22. Apparently transposons only jump to sites at where sequences have been duplicated before. So, they do not integrate at random.

23. Preinsertional duplications are not known. Duplications occur in the process of insertion. They are a consequence, not a presupposition of insertion.

24. Transposons exhibit homing tendency; they jump primarily on their own chromosome.

25. There is a certain tendency for transposons to be integrated on the same chromosome. However 50% of the insertions occur on other chromosomes. In principle, any chromosome can be the target of insertion.

Integration of transgenes is irreversible; insertion of transposons is reversible

26. Mutations through the insertion of transposons are reversible; the integration of transgenes is irreversible.

27. It is possible to stabilise the insertion of transposons to the same degree as the integration of transgenes, through changes in the transposon or the outbreeding of gene sequences which are necessary for transposition.

28. Reversibility of transposition means that transposons pose a higher risk of unexpected side-effects than transgenes. Transposons can change the genomic context again when they leave the site of insertion. Frequently they leave "footprints", i.e. mutations and changes in the pattern of gene regulation, at the site where they insert. This may change gene functions, for example, in mutations of the flower colour.

29. Mutations which can be induced by insertion of transposons will mostly concern recessive genes; far-reaching mutations are likely to be eliminated immediately.

30. Transposons can induce mutations which lead to dominant alleles; they can, for instance, enhance the rate of reproduction.

31. The differences between transposons and transgenes must be assessed in totality. Transposons are reversible and the frequency of transposition depends on the developmental stage of the plant. This warrants the conclusion that transposons, in contrast to transgenes, have a function for the plant and are regulated by the plant.

32. It has never been shown that the activity of transposons, except for the frequency of transposition, is regulated by the plant itself.

This was the reconstruction of the state of argumentation with respect to the comparison of transposons and transgenes. This reconstruction was presented to the participants of the technology assessment for examination. It was the basis the organisers used to derive tentative conclusions which they proposed at the final conference. In these conclusions, they first emphasised that, of all the differences which were claimed to exist between transgenes and transposons, only reversibility and site-specificity of integration could have any bearing for the question whether context disturbances (insertional mutations) and hence the risk of unexpected side-effects were comparable for transgenes and transposons. With respect to reversibility, it was concluded that the integration of transposons is in fact reversible; but this means that transposons are likely to have more rather than less side-effects on the host plant than transgenes, because they can induce mutations both at the site to which they move and at the site where they leave. With respect to site-specificity, it was concluded that the claim was wrong: transposons do, in fact, integrate at random. The representative from the Öko-Institut tried to make the case that there was a controversy in science over this question, by referring to Fedoroff (1991) for support in this respect (see statement 16, above), and she did not seem to be convinced by the end of the discussions. Therefore, to clarify the issue further, the organisers offered to contact Fedoroff and have her expert statement included. However, the Öko-Institut did not want to use that offer. Accordingly, the organisers then felt that it was legitimate to propose the following summary of the conclusions:

> ”There is neither empirical evidence nor a theoretical model to show that transgenes could induce more disturbances of the genomic context, or a different kind of disturbance, than transposable elements which move around in the plant genome naturally. The gene locus in which transposons are integrated, is not regulated by the plant. There is no controversy in science with respect to this finding.”

This conclusion settled the issue and the controversy was put at rest within the technology assessment procedure. At the final conference, even the critics admitted that transposons and transgenes are comparable with respect to the impact they might have on the genomic context. They merely pointed out that this finding is valid ”as far as we know today”. This proviso was accepted by all, because it is evident and applies to everything we know.[9]

10 The closure of the participatory procedure

When the final conference convened in June 1993, the representatives from the environmental groups and their associated research institutions declared that the participatory approach of the technology assessment had failed, in their view, and they withdrew from the procedure. The main reasons they gave for this action were that:

- honorary involvement in the procedure took up too many of their resources,
- the industrial companies and scientists involved in the procedure had created a fait accompli by applying for the release of transgenic herbicide-resistant plants without informing the other participants or presenting their plans for discussion in the procedure,
- the volume of information and time pressure made it impossible to examine the documents prepared for the final conference and to formulate adequate responses to the proposals made,
- the influence of the WZB working group was too strong and there were doubts as to the fairness and impartiality of the summary of results.[10]

At this conference the conditions for the further participation of the environmental groups were discussed with them. It was pointed out in particular that the final conference was designed explicitly to hear any criticism they might have with respect to the substance of the results presented so far, and to allow for further substantiation of dissenting opinions. The environmental groups then offered to continue to participate under the condition that roughly 20% of the final synthesis report be allocated to them to present a dissenting opinion, and that DM 50,000 be made available to prepare this opinion. These conditions could not be met because the funds for the procedure had been exhausted. The demands were subsequently withdrawn, and the environmental groups confirmed their decision to leave the final conference. Their positions were still represented in the conference, however, because these views were also held by a number of participants from universities and (albeit in fewer cases) from governmental agencies.

The argument that industry had undermined the basis of participation by going ahead with applications for the release of transgenic herbicide-resistant crops is a serious one. A participatory technology assessment requires that cooperation be stabilised and that participants develop some kind of trust among themselves and that they remain loyal to the procedure. On the other hand, given the divergent interests no excessively high loyalty can be demanded, especially not with respect to the behaviour of the participants outside the procedure. In general, it would seem unrealistic to require that, in the course of a (voluntary) technology assessment, a moratorium on the technology it investigates be upheld. No company could afford to participate if the condition were that it stop developing or using the technology during the period of assessment (which could be years).

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[9] See section II A5 below. Even the representatives from the Öko-Institut among whom the drafts of final conclusions had been circulated, did not come back to their original claim. They instead demanded a shift in the burden of proof: The assumption that the consequences (of transgenes an transposons) are different had been classified as speculation, ”although no ‘proof’ against this hypothesis has been found” (letter from March 16, 1994 (see van den Daele 1994: 52). In the political debate outside the technology assessment procedure the Öko-Institute continued, however, to repeat the original claim that transposons have different impacts on the genomic context than transgenes—even with reference to the same literature (Fedoroff); thus, they were completely unimpressed by the arguments in the technology assessment, see Weber (1996).

[10] See also Gill (1993).

The coordinating committee faced this problem a year before the final conference took place, when it became known that one of the participating industrial firms was going to submit an application for field tests with genetically modified sugar beet and a herbicide resistance gene as the marker. The majority of participants in our technology assessment felt that the application would jeopardise the whole procedure, but a formal decision in the coordinating committee was blocked by a veto. The problem "disappeared" because the firm agreed to postpone their application until after the final conference. Unfortunately the problem came back because the final conference was postponed for half a year.[11]

The argument that the methodology applied by the WZB working group in preparing the final conference placed constraints on the autonomy of the participants is correct. The participants were required to work their way through a more or less predefined agenda. Those who prepare a draft conclusion have some power to define and select. On the other hand, draft conclusions are indispensable in a meeting of fifty or more persons if nonconclusiveness of the deliberations is to be avoided. So the only way out, it seemed, was to prepare drafts and have the participants check whether the WZB working group and the organisers had used their power justly and impartially.

The participants had the opportunity to criticise the drafts submitted, and to revise or replace them, both at the final conference and in writing thereafter. Written exchange was also the form by means of which the participants continued to be included in the preparation of the final version of the material to be published from the technology assessment. All such drafts were circulated among the participants. Commentaries, unless incorporated, were also published. This rule entitled all the participants to publish their own opinions and evaluations together with the results of the procedure. However, it had been decided by the coordinating committee very early in the procedure that uncommented, dissenting opinions, merely to be tacked on to the final synthesis report, were not admissible. The fact that the environmental groups came back to this issue in the negotiations over their withdrawal from the final conference showed that they had not really accepted this rule as justified. Apparently, the environmental groups had ambivalent feelings about being involved in a procedure in which they could not control the findings. On the other hand, it was probably this very rule which ensured that all the participants committed themselves fully to the dynamics of argumentation and resisted the temptation to downgrade the technology assessment from the outset to just another public forum where all the groups again just display their differences of opinion. With these procedural rules, "the last word" in the technology assessment was, to a certain extent, reserved for the organisers. Further criticism could then only come from "outside", after the final synthesis report had been published. What this means for the concept of participatory technology assessment requires further analysis.

11 Some structural problems of participatory technology assessment

It is certainly not enough to attribute the decision of the environmental groups to leave the technology assessment in the final phase solely to the historical, contingent circumstances of this particular procedure, that is, to the constellation of actors involved and to mistakes in the steering of the procedure. Participatory technology assessment, as such, is a politically ambivalent structure, the stability of which always remains precarious. To this end a few final remarks follow.

Participation in the technology assessment procedure does not mean that the opposing sides will always have control over the entire procedure, nor can they make it dependent on their factual consensus. The participants have control over the process but not over the results.

Technology assessments are essentially investigatory strategies which aim to produce information. This sets them apart from purely political dialogues in which discussions take place primarily over the goals and criteria for the desirable development of society. The validity of information produced in this kind of procedure is not conditioned by the acceptance of the participants. In terms of social theory, the medium of social integration in this case is not social but

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[11] It should be mentioned that the environmental groups, too, showed limits in their loyalty with the technology assessment. They presented their version of the findings of the assessment in a press release before the discussions in the technology assessment had been finalised. The coordinating committee again refused a formal verdict, remarking only

> "that it neither wishes nor is it empowered to control public statements on transgenic herbicide-resistant crops by participants in the procedure" (Minutes of February 5, 1993).

The majority of the coordinating committee merely criticised the fact that the statement to the press created the impression that the procedure had been terminated.

cognitive. The participants are not really in a situation wherein consensus can be deliberately granted or withheld. Consensus becomes irrefutable because what is viewed as knowledge in society and what corresponds to generally shared valuations cannot be deliberately dismissed.[12]

Discursive procedures trigger an argumentation dynamic which can neither be contained nor controlled by any individual participant. A frame of argumentation is also used in public communication, for example, in the media, when opposing sides take up controversial positions. But the truth is that the parties seldom really argue. Recourse to proof and reason serves only to present one's own position more convincingly. In our technology assessment, by contrast, since it was organised as an on-going dialogue among those present, argumentative debate is unavoidable. The individual positions must be defended against the on-going emergence of counter-arguments. Whether a position proves to be viable under these circumstances can neither be predicted nor controlled.

Information orientation and discursivity preclude a complete control of results through participation. Despite this, the strategy of information seeking remained undisputed to the end. There seems to be no alternative, because the public controversy to which the technology assessment refers is a debate about empirical arguments, above all, a debate about the potential risks and expected advantages of the technology. The opposing sides in the procedure continue to be bound to the framing they have chosen for the contested issues in the public debate. If they give the impression that empirical information does not really matter for them, they not only exclude themselves from the discursive procedure, they also lose face in public. Anyone who indicates that he or she is not interested in arguments, but simply in interests and power, can neither stake claim to participation in the technology assessment nor expect, through such participation, to gain political profit for his or her own campaign.

In controversies about empirical questions, and, therefore, in arguments about the consequences a technology might have and about what we know or do not know of such consequences, recourse to science is compelling. One cannot present one's position in public as scientifically substantiated and then cast fundamental doubt on science as a neutral third instance in a technology assessment procedure. Participation in the procedure implies the readiness to submit oneself on empirical issues to the judgement of science [13].

Participation offers options to influence the formation of judgement in a procedure, but it does not call on the conflicting parties to sit in judgement on themselves. This is ruled out in any case, because the conditions for participation are, in principle, symmetrical, i.e. the parties must have equal rights. Where consensus cannot be achieved the final judgement must be left to neutral observers of the procedure. The fact that a group or party did not agree to the results proves nothing more than lack of consensus. It may, of course, be taken by the public at large as an indicator against the fairness of the procedure or the viability of the results. An increase in rational conflict management can only be expected of a technology assessment procedure if it at least offers an opportunity for the public not to rely solely on indicators of this kind, but to examine the matter at hand by themselves.

It is doubtful whether, in a participatory procedure, the rule should be that no one is allowed to occupy the role of a neutral third instance, which to a certain extent was taken, in our case, by the WZB working group and the organisers. The consequence would be that we would have to do without presenting results whenever an issue remained controversial; the presentation of the controversy would then be the only result. This would be in contradiction to the declared political aim of a technology assessment. Political controversies about technology are the starting point and subject of technology assessment. The public has a right to efforts at least being made, in procedures of this kind, to determine the state of knowledge on controversial subjects. A technology assessment must give an answer to the question whether risks that are publicly decried actually exist, or whether the technology is likely to provide the benefits claimed. Criticism of the methods through which the procedure arrives at conclusions must also be submitted to the scrutiny of the general public.

Of course, it is conceivable that a never-ending dispute will prevail in society, concerning what organisations or individuals could represent the neutral instance of science. But even then, the

[12] Georg Simmel talks about "intellect" as the medium of social coordination; cf. details in Döbert (1994).

[13] In our technology assessment, the validity of scientific findings was not an issue of debate. Nor was any role played by the epistemological metatheories by means of which sociologists sometimes play down scientific claims to validity as "social constructions" and instead claim a pluralism of social forms of knowledge which are mutually incompatible but supposedly all equally valid.

opposing sides could not demand that they themselves be given this responsibility. In that case, information and technology assessment would no longer be credible at all as a means of conflict resolution. However, it should be noted that the radical dismantling of science as an ideology would be politically dysfunctional, too. If one really could argue that whoever speaks in the name of science is in fact only presenting political interests, then only power counts, and votes could and would have to be taken immediately. There would be no point in commissioning expert reports (not even by ”critical” experts). If the results only reflect the interests of the respective parties then, for the public at large, it would be cheaper for it to inform itself directly about these interests.

A participatory technology assessment commits the parties of the political conflict over new technology to cooperation in a procedure with an uncertain outcome. From the angle of the observing public (including parliaments, courts, etc.) this is an advantage. Through their participation the parties lend legitimacy to an attempt in which they control the process but not the result. Whether participation is politically attractive under these conditions will depend on how high the normative expectation is that conflicts will be dealt with in discursive form, i.e. in the form of argument. If these expectations are high, conflicting parties will not be able to withstand the demand for new discursive fora, or reject participation without ensuing political costs.

Procedural fairness is the essence of participatory technology assessment. If this principle is violated then withdrawal from the procedure can be expected and is legitimate. However, one cannot legitimately withdraw from a fair procedure simply because the emerging results contradict ones own strategic interests. Nevertheless, in terms of ”Realpolitik”, withdrawal must be expected in such a case, too.[14] It must also be expected that arguments refuted in a participatory technology assessment will nevertheless continue to be used outside and after the technology assessment, as long as these can still impress the public. Such inconsistency may be criticised; it should not be taken as a proof, however, that, in principle, participation in discursive procedures is not a suitable form of political conflict resolution.

[14] And it can be a ”rational” move in terms of calculation of political costs; see Döbert (1994), Holzinger (1996) for an explanation of why the environmental groups withdrew from the technology assessment before the final discussion of the conclusions.

PART II: EMPIRICAL FINDINGS — IMPACTS AND CONSEQUENCES

Throughout the technology assessment, empirical questions about the possible consequences of transgenic herbicide-resistant crops were kept clearly separate from normative questions about assessing these consequences. Contrary to the relativist rhetoric often exposed in the social sciences that facts are irresolvably confounded with values, the participants in our technology assessment treated questions of fact as categorically distinct from and logically prior to questions of value.[15] Thus empirical questions such as: *Does a risk or a benefit exist? What can possibly happen? How likely is it to happen? What is the causal mechanism? Are the consequences of genetic engineering comparable to the consequences of classical breeding?* were always distinguished from normative questions such as: *Is the risk acceptable? Is the benefit appreciable and worth the risk? Who shall bear the burden of proof in the case of uncertainty? Are the alternatives to genetically engineered crops preferable?*

Empirical questions can, in principle, be answered scientifically and are a proper domain of experts. Consensus on these questions must (given the requisite knowledge) be possible. Normative questions involve moral and political judgement, and are the domain of lay persons as citizens. These questions may reflect legitimate differences of values and preferences, and must then be dealt with in their variety and contradiction. The following sections summarise the empirical findings of the technology assessment first. The starting point is the examination of possible risks from the genetic modification of crop plants.

A BIOSAFETY ASPECTS OF TRANSGENIC PLANTS

The assessment of technology is not the regulation of technology and cannot, therefore, be confined solely to issues of safety. It must extend into broader issues of social and political implication, namely, benefits and uses, available alternatives, and cultural meaning of the technology, and into visions of the future development of the society. In many respects, such an assessment will go beyond the existing law, or even beyond the political mandate of the modern state. In public debates, however, there is a prevailing tendency to concentrate discussions on the safety aspects of new technology. This is probably due to the fact that diffuse anxieties about new developments can easily crystallise around risk scenarios, and that the latter are at the same time a powerful operationalisation of the criticism of new technology because they fit into the established frameworks of restrictive political regulation.[16]

Concerns about risks to human health and the environment also dominate the debate over transgenic herbicide-resistant plants. A main report of our technology assessment was, therefore, commissioned from the Öko-Institut, Freiburg, which has been the most outspoken and articulated source of criticism of genetic engineering in Germany during the last decade. Thus it was guaranteed that the best available counter-arguments were placed on the agenda. Geneticists were invited to comment on these arguments.[17] Additional reports were commissioned to examine in detail the biosafety issues associated with the possibility

- that unexpected and undesirable physiological changes (pleiotropic effects) occur in transgenic herbicide-resistant plants,
- that the transgene (and the trait of herbicide resistance) is propagated to unrelated organisms (such as soil bacteria or other plants) via horizontal gene transfer,
- that the transgene "escapes" from cultivation, either in feral populations of the crop plants themselves or through hybridisation with wild relatives.

[15] The reference to objective knowledge in the technology assessment by both advocates and critics of transgenic herbicide-resistant crops is further analysed in van den Daele (1996).

[16] Cf. van den Daele (1993).

[17] Expert report commissioned from Dr. B. Weber (Öko-Institut, Freiburg): "Evolutionsbiologische Argumente in der Risikodiskussion am Beispiel der transgenen herbizidresistenten Pflanzen"; commentary by Dr. A. Heyer*, Prof. H. Saedler** and Prof. L. Willmitzer* (*Max-Planck-Institut für molekulare Pflanzenphysiologie, Golm; **Max-Planck-Institut für Züchtungsforschung, Köln), in: *Materialien zur Technikfolgenabschätzung, Heft 5* (see appendix).

We summarise the conclusions from the discussions among the participants in the technology assessment. At the heart of these discussions was the question of whether there are specific risks implied in genetically modified crops, which would not occur were the crops modified through techniques applied in conventional plant breeding. For the details of the expert reports we must refer the reader to the materials published in the WZB discussion paper series (see appendix). Some additional references to recent developments and findings are added in footnotes. The discussions in the technology assessment raised questions which follow closely the themes of the public debate. We organise the summary of conclusions for each topic around these questions.

1 Physiological side-effects and food safety: Are toxic or allergenic substances to be expected in transgenic plants?

Lines of consensus and dispute

Transgenic herbicide-resistant plants are supposed to express the product (enzyme) of the transferred herbicide resistance gene in the metabolism of the plant cells. The intended effect is that the plant will become herbicide-resistant. However, the gene transfer can have unintended side-effects on the plant metabolism, through which other properties of the plant may be altered.[18] In some cases, it will be possible to anticipate potential side-effects using the information on the transgene and its gene product, and on the properties of both the donor and the host organism. It can, for instance, be tested whether proteins produced by the inserted transgene are toxic or allergenic for humans. It can be tested whether the transgene inadvertently transmits the allergenic potential of the donor organism or enhances the allergenic potential of the host organism.[19] One can, however, only test for known allergies. There is no way to predict whether a new protein from a donor organism which has no history as a known allergen (and has perhaps never been part of our food) might induce allergies in some consumers.[20] In many cases, therefore, the possible side-effects of gene transfer on the metabolism might in fact be completely unpredictable.

In the technology assessment, four mechanisms which could lead to unintended physiological changes in transgenic herbicide-resistant plants were discussed:

1. Effects of the nonselective herbicide. A number of herbicide resistance genes transfer mechanisms through which derivatives, conjugates etc. of the herbicide are formed in the plant. These substances may be toxic. They may also interact with other substances and influence secondary metabolic processes in unforeseen ways.

2. Effects of the transgenic gene products. The herbicide resistance gene introduces a new gene product into the metabolism of the host plant. Interactions between this new product and substances which already exist in the plant can only be predicted to a limited extent. This will, above all, be true when the transgene encodes a resistance mechanism which is completely new in the metabolism of the host species. In this case the gene product will hit upon metabolic substrates which are different from those in the donor organism. It could interact with such substrates and form new and unexpected metabolic products.

3. Effects of the locus of transgene insertion on the expression of the transgene. Gene transfer techniques do not, as a rule, allow a site-specific integration of transgenes in the host genome. Transgenes may be inserted at frequently expressed sites, but also at inactive ones. The locus of insertion can therefore influence the expression of the gene product (positional effect). Variations in expression, and in particular over-expression, could lead to unexpected changes in the plant metabolism.

4. Effects of the locus of transgene insertion on the expression of endogenous plant genes. The metabolism of the host plant can be affected by the insertion of the transgene as such, independent of the gene products. If the transgene is inserted into an active plant gene then this gene will be interrupted (insertional mutation). As a result, its gene product may not be produced at all or to a different degree. In addition, the regulation of neighbouring genes may also be

[18] Expert report from Prof. B. Böger (Lehrstuhl für Pflanzenphysiologie und Biochemie der Pflanzen, Universität Konstanz): "Mögliche pflanzenphysiologische Veränderungen in herbizidresistenten und transgenen Pflanzen und durch den Kontakt mit Komplementärherbiziden"; commentary by Prof. R. Weidhase, Halle, in: *Materialien zur Technikfolgenabschätzung, Heft 2* (see appendix).

[19] Thus, tests revealed in a recent case that the transformation of soybeans with a transgene from paranut can confer the known allergenic potential of the nuts to the soybeans; Nordlee *et al.* (1996).

[20] Cf. Frank-Oberspach and Keller (1996: 55).

influenced.[21] These variations in gene expression can also lead to unexpected and unforseeable changes to the plant's metabolic pathways.

Side-effects of herbicides on the metabolism of resistant plants are a standard problem in the regulation of herbicides, they will be discussed below.[22] Side-effects of the gene transfer play a key role in many debates over the possible risks from transgenic plants. They are the hypothetical starting point for a number of risk scenarios. This section deals with impacts of the gene transfer which might affect the food safety of transgenic plants. The following sections discuss possible environmental consequences.

The participants in the technology assessment agreed that metabolic processes in plants are, in general, quite variable. They vary with changing environmental conditions and as a result of modifications caused by breeding techniques. Pleiotropic effects through uncontrolled interactions in the plant metabolism are abundant in the practice of breeding and have in many cases led to "bad surprises", e.g. unforeseen and unintented morphological changes, yield losses, new substances or new levels of expression of substances in the plants. In some cases, such effects have been shown to be toxic or allergenic.[23]

That physiological side-effects are in fact a real problem has been illustrated throughout the technology assessment with examples from the history of traditional breeding. Quite plausibly, therefore, the main controversy among the participants focused on the question, whether there was a special risk of unintended physiological changes in the case of transgenic plants. Should we expect more or more dramatic side-effects in the metabolism of transgenic plants than in the metabolism of plants modified by conventional breeding techniques?[24] Discussions dealt with the comparability of side-effects in general (question 1 below) and with three mechanisms why side-effects might be more likely in transgenic plants: nontarget or pleiotropic effects of the transgenic gene product (change of substrates), instability of transgene expression, and effects of the insertion of transgenes at the DNA level (positional effects and insertional mutagenesis) (questions 2-4).

Question 1: Can unintended physiological side-effects in transgenic herbicide-resistant plants lead to the formation of toxic or allergenic substances? Are such side-effects more likely to occur in transgenic than in nontransgenic plants?

Conclusions from the discussion

1. In the case of transgenic herbicide-resistant plants, new substances are introduced into the plant metabolism: the gene product of the transferred herbicide resistance genes and also (depending on the resistance mechanism) the transformation products, conjugates etc. of the nonselective herbicide. The new substances can enter complex interactions with the host cell metabolism which may give rise to unexpected and unforeseeable phenotypic consequences. This includes the possibility that plant substances may be formed which are toxicologically significant (or which are carcinogenic, mutagenic or allergenic).

2. Shifts in plant metabolism and new plant substances also occur as a result of conventional breeding or fluctuations in the plants' natural environment, such as climate variations or attacks by pests. In the latter case it has been shown that new, humano-toxic plant substances are induced.

3. It is plausible to assume that different techniques to modify plants might have different side-effects. Genetic engineering has the potential to transfer genes (and gene products) from distant, nonrelated species, which could not be introduced by conventional breeding techniques. Side-effects on the plant metabolism resulting from such transfers represent a specific risk from genetic engineering in the sense that without genetic engineering, the transfer would not be possible and therefore the side-effects could not arise. In this sense, however, the various techniques of conventional breeding (such as mutagenesis or intergenera crossing) would also represent specific risks, since the side-effects they could have on the plant metabolism would

[21] Effects of the locus of transgene insertion have been discussed in the technology assessment as "disturbance of the genomic context"; see also below section II A5.

[22] Cf. section II B2.

[23] For instance, hybrids between established potato varieties and related wild types have shown excessive (toxic) concentrations of glycalcaloids (van Gelder 1991: 121); the allergenic potential of apples became clinically visible only after the breeding of new varieties in the 1960s (Aulepp and Vieths, 1992). Frank-Oberspach and Keller (1996: 43/51) refer to these examples.

[24] "Conventional" here refers to all methods of breeding currently used and accepted that do not involve genetic engineering. These methods include far more than merely the crossing of individual plants of the same species, through which nearly identical genes (alleles) of closely related plants are mixed. In a number of cases crossing between different species has been possible; mutagenesis can be used to alter existing genes so that new gene products are formed.

not occur if the techniques were not applied.

4. There is up to now no evidence that the technique of gene transfer can cause metabolic side-effects in transgenic plants, which are of a different type or quality than those occurring in nontransgenic plants. Any scenario that has been devised to anticipate possible damage from unexpected physiological changes in genetically engineered plants applies equally to plants which have been created by conventional breeding. With either technique, risks must be expected whenever a problematic trait (or gene product) is transferred. Whether the trait is transferred through gene transfer or through breeding does not seem to make a difference.

5. The claim that transgenic plants involve specific physiological risks was defended in the technology assessment as a hypothesis. A number of reasons were offered to account for the possibility that gene products encoded in transgenes might have more (or more undesirable) side-effects on the plant metabolism than are to be expected either from fluctuations of the natural environment or from modifications through conventional breeding:

- because of evolutionary adaptation (co-evolution) plant substances that occur naturally in food plants are likely to be nonharmful to human beings;
- the toxic/mutagenic potential of natural substances is neutralised by synergistic effects in the plant metabolism;
- in conventional breeding, unexpected side-effects are limited by regulatory cycles within the plant;
- since transgenes introduce gene products which were never in the plant metabolism before, they will lead to more and qualitatively different side-effects;
- the insertion of transgenes disturbs the genomic context of the host plant and will, therefore, induce more and different kinds of side-effects.

The last two points are dealt with in questions 2 and 4 below. Consideration of the first three points yields the following:

6. *Co-evolution.* The reference to co-evolution of human beings and their food plants is unclear. Humans have adapted to their food plants by selecting those plants which they found edible. Co-evolution may help to explain why the human genome encodes basic metabolic mechanisms for detoxification and immune reaction which ensure that plants are edible. However, many plants still remain toxic for humans, and in these cases, by definition, there has been no adaptation through co-evolution. On the basis of evolution theory, there is no reason to assume that substances which are naturally formed in plants are in general less problematic in terms of toxicity than substances which might be newly induced in transgenic plants.

7. *Synergism.* There are some indications (although disputed in science) that a mutagenic potential found for isolated plant substances can be neutralised by synergistic effects within the plant as a whole. These substances would then be harmless, as long as they remained integrated in the metabolism of the plant. If this were really the case it would also be true for transgenic plants. It is inconceivable that synergism should only operate to neutralise problematic substances formed as a result of natural fluctuations or metabolic interactions in conventional crop plants, and not substances occurring as side-effects in transgenic crop plants.

8. The Öko-Institut argued that the neutralisation of problematical substances through synergism may depend on a ”balance” within the plant, and that the gene transfer technique may be particularly prone to jeopardising this balance. Whether or not evolution theory is compatible with assuming such a ”balance” of substances in natural plants (which after all would be defined in terms of advantages for human consumers of the plant and not of advantages for the reproduction of plant itself) need not concern us here. It certainly cannot be assumed to exist for the combination of substances possible in the domesticated plants we use for cultivation. It is incomprehensible that there could be a natural balance in plants guaranteeing that, for example, combinations of plant substances with new gene products induced by mutagenesis, transposons or additive lines are not toxic to humans.

9. *Regulatory cycles.* It is plausible to assume that plants rely on regulatory cycles to limit fluctuations in their metabolic processes and exclude the formation of new substances that do not fit the species. Transgenes may escape these cycles. The same, however, may also be true for products of conventional breeding. In the case of cross-breeding between closely related plants which are almost identical, the metabolism will remain under the effective control of the regulatory cycles of the species—although even then a wide range of surprises are possible. However, in the case of mutagenesis, for example, completely new substances may be produced which do not fit the plant’s own regulatory cycles.

Question 2: Is there a special risk of unexpected side-effects in transgenic plants due to the fact that gene products can be introduced which have never been in the metabolism of the host plant and which might find other metabolic substrates than in the donor organism?

Conclusions from the discussion

10. In theory, unforeseen metabolic side-effects are more likely to occur in transgenic than in nontransgenic plants, if new metabolic pathways are transferred which are not naturally established in the host plant species. In this respect, it is unimportant whether the transgenes originate from bacteria or plants. In either case, the gene product can end up in a metabolic context which is very different from the one in which it had operated in the donor organism, and it can interact with new substrates.[25]

11. This additional risk factor is absent when transgenes confer metabolic pathways which have already been established in the host plant. However, the potential of genetic engineering lies exactly in the transfer of genes from distant, nonrelated organisms. Transgenic products will, therefore, quite often involve metabolic pathways which are new to the host plant and could not have been introduced by traditional breeding.

12. Chemical tests can, to a certain degree, control whether or not the transgenic gene product is likely to switch to new substrates. Substrate specificity *in vitro* does not, however, prove that unexpected substrates will in fact not be found *in vivo*, i.e. in the plant. Not all plant substances are known, nor would it be possible to test for all of them in advance.

13. A comparative assessment of the probability of physiological side-effects in transgenic and nontransgenic plants would actually have to take into account two countervailing factors: On the one hand, side-effects are theoretically more probable in the case of transgenic plants, because (and insofar as) new metabolic pathways are introduced which have not yet been established in the host plant. On the other hand, side-effects are theoretically more probable in nontransgenic plants because (and insofar as) conventional breeding techniques reshuffle many different genes (alleles) and modified gene products in a quite uncontrolled manner, any of which has some chance to interact in unexpected ways with existing metabolic processes. In contrast, gene transfer only introduces a single, clearly defined gene product. It is nonetheless impossible to say how these two factors weigh against each other in the final analysis. We are dealing with side-effects which are conceivable, but undetermined and unforeseeable. For such, no quantitative estimate of the probabilities involved is possible.

14. In sum, the hypothesis that more physiological side-effects will occur with transgenic than with nontransgenic crop plants is neither more nor less plausible than the converse hypothesis, that there will be fewer side-effects in transgenic than in nontransgenic crop plants. Neither of these statements can be proved or disproved. Theoretically, one can derive that fewer side-effects can be expected in transgenic crops than in nontransgenic crops in cases where metabolic pathways are transferred which have already been established in the host plant species.

Question 3: Do instabilities in the expression of transgenes entail specific risks of physiological side-effects for transgenic crop plants?

Conclusions from the discussion

15. Variations in the expression of genes are a normal phenomenon of plant metabolism. They are not a problem specific to transgenes, but occur equally in nontransgenic plants and in response to fluctuations in the natural environment of the plant, such as climate changes or attacks by pests.

16. Variations in the expression of transgenes are certainly not in a meaningful way controlled by the normal regulatory mechanisms of the plant. However, this is not a problem of transgenes alone. Full regulation of gene expression by the plant itself can only be presupposed for wild plants, at the most. Such plants may be programmed to switch genes on and off in response to natural environmental factors in a way that is physiologically and ecologically useful (i.e. reproductively advantageous) to the plant. Whether the same holds for crop plants with genes which have been selected by breeding to optimise agricultural utility, is already doubtful. The regulation is certainly lacking for genes which have been modified by mutagenesis. Such genes will still be subject to plant regulation, as long as the mutation is confined to nonregulating sequences. However, the altered code area of a mutated plant gene is of just as little physiological and ecological ”meaning” to the plant (adaptive

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[25] Regal (1994: 11) assumes that *pleiotropic expression* may be enhanced when a ‘foreign’ gene product from unrelated species is transferred, because studies showed ”that certain types of molecular cross reactions between an enzyme and tRNAs are stronger when the molecules come from more distantly related species”.

value in evolutionary terms) as a gene from a bacterium introduced by gene transfer.

17. Conversely, the fact that regulatory plant mechanisms operate does not indicate that the risk is smaller. Variations of gene expression which are ”meaningful” for the plant in evolutionary terms, may nevertheless induce metabolic changes which are not safe in terms of the human uses of the plant. The normal responses of plants to external stress often involve the production of humano-toxic substances.

18. Even if it were shown that transgenic herbicide resistance genes are more frequently switched off under stress conditions than the plant’s own genes, this would still not mean that there was an additional physiological risk. Resistance genes which are switched off will not be able to affect the plant metabolism. What will happen is that the plant dies when the nonselective herbicide is applied.

19. Herbicide resistance transgenes (for instance, PAT genes in the case of resistance to glufosinate) that are switched off may have an increased mutation rate. This does not imply that they are more likely to induce unexpected metabolic side-effects. Theoretically, mutations of nonexpressed (methylated) genes will be more frequent, exactly because they have no impact on the plant metabolism and therefore are not subjected to selection pressure. The mutation of cysteine to thymine, which is possible for methylated PAT genes, can at the same time switch the gene on again. So, metabolic effects become possible; they can, however, be assessed if the sequence of the mutated gene is known.

Question 4: Does the insertion of transgenes represent a disturbance of the genomic context which could lead to unexpected and unforseeable changes in the plant metabolism? Are disturbances of the genomic context a risk which is specific to transgenic plants?

Conclusions from the discussion

20. Since the available gene transfer methods do not, as a rule, allow the gene locus to be targeted, at which the transgene is inserted, unforeseen insertional effects at the DNA level are to be expected. The locus of integration can influence the expression of the transgene itself (positional effect), and the intermittence of the transgene can alter the expression of plant genes at or near the locus of integration (insertional mutagenesis, termed ”context disturbances” by the Öko-Institut). In both cases, the result could be that respective gene products are either not formed at all, or not at required or normal levels and the plant metabolism is changed.

21. However, positional effects and context disturbances (insertional mutations) do not arise solely as a result of gene transfer. They also occur in conventional breeding, for example, in the case of chromosome breaks and translocations during meiosis. They can lead to unexpected changes in the metabolism and the phenotype of the plant. Occasionally positional effects and context disturbances (e.g. from transposons) have been used by breeders as a source of genetic variation for the development of new plant varieties.

This conclusion was contested in the technology assessment. The Öko-Institut argued that due to the ”special quality” of genetic engineering, unexpected effects at the DNA level (disturbances of the genomic context) should be different in transgenic and nontransgenic plants. Since this argument played a key role in the debate on both food safety and environmental safety, it will be considered in detail in section II A5 below.

2 Horizontal gene transfer: probability and possible consequences

Horizontal gene transfer means the transfer of genetic material between organisms from different species which otherwise cannot be crossed. Such a transfer is possible in nature. As a rule, however, it should be a rare event, because of the boundaries which have been established during evolution prohibiting the exchange of genetic material between noncrossing species.

Horizontal gene transfer seems to occur frequently between prokaryotes (mainly through conjugation), but only in a few cases has it been shown to operate across kingdoms of organisms, for example, from bacteria to plant or animal cells. Our technology assessment had to examine whether herbicide resistance genes from transgenic crop plants could be spread to soil bacteria or to other plants through horizontal gene transfer, and whether this represented a specific risk from transgenic plants.[26] Discussions concentrated on two questions: How probable is the horizontal transfer of the herbicide resistance

[26] Expert report commissioned from Dr. I. Broer and Prof. A. Pühler (Institut für Genetik, Universität Bielefeld): ”Stabilität von HR-Genen in transgenen Pflanzen und ihr spontaner horizontaler Gentransfer auf andere Organismen”; commentary by Dr. B. Tappeser (Öko-Institut), in: *Materialien zur Technikfolgenabschätzung, Heft 3* (see appendix). See also Schlüter *et al.* (1995), Sandermann *et al.* (1997).

genes? What effects could such a transfer have in a worst case scenario?

Discussions of the first question were mainly about whether and under what conditions genetically modified plant genes are more likely to be propagated through horizontal transfer than unmodified (endogenous) plant genes. Natural transfer rates served as a frame of reference. These included not only the transfer rates for endogenous plant genes, but also those for bacterial genes. The latter are considered as the appropriate reference in cases where herbicide resistance genes originate from soil bacteria. In those cases the direct transfer of such genes from the donor organisms to other soil bacteria should be more likely than the indirect transfer via transgenic plant cells.

Discussions of the second question focused on the effects horizontal gene transfer might have on the biodiversity of microfloral populations in the soil, and on the chemistry and hence functions of the soil. Participants agreed that such effects are possible. They disagreed, however, about whether horizontal gene transfer should in fact be counted as a significant cause of such effects, since comparable effects can or will be produced at the same or greater levels (or with a higher probability) by common agricultural practice, such as the use of herbicides, ploughing, or crop rotation.

The counter-argument to this comparison was that the ”special quality” of the techniques of genetic modification might also involve a special quality of consequences of these techniques. For that reason it was assumed that horizontal transfer of transgenes could lead to changes in bacterial metabolism (and thus also to changes in the chemical and dynamic processes in the soil) which were different to those caused by other practices which also modify soil processes.

Question 1: Is it to be expected that herbicide resistance genes will spread from transgenic crop plants to bacteria and to other plants through horizontal gene transfer? Does such transfer represent a specific risk from transgenic plants?

Conclusions from the discussion

(a) The probability of gene transfer to soil microorganisms

1. Horizontal gene transfer is not a specific feature of genetically modified plants. Transgenes coding for herbicide resistance can only be transferred from transgenic crop plants by the same mechanisms which operate for horizontal gene transfer in nature anyway. These mechanisms can just as well propagate endogenous genes from plants which have not been genetically modified; or they can propagate genes directly between soil bacteria without transgenic plants as an intermediary.

2. Horizontal gene transfer will, in general, be a rare event in nature. Otherwise, the clear differentiation of species, as we observe it, would not exist. Low transfer rates must also be assumed to account for the limited distribution of resistance to antibiotics in the soil. A number of soil bacteria have resistance genes producing antibiotics to attack other microorganisms. The resistance genes have not, however, spread to the attacked microorganisms in the course of evolution. Transfer of these genes between soil bacteria has only been observed under laboratory conditions. (Transfer rates of the resistance genes are also high under the special selective conditions of clinical applications of antibiotics.)

3. The natural rate of gene transfer is unknown. It will, however, by no means be high enough to warrant the assumption that every gene has probably already been tested and selected for in every possible environment. Whether natural gene transfer is frequent enough to say that any further increase of the transfer rate which might result from transgenes would be negligible, cannot be decided.

4. The probability that transgenes for herbicide resistance might be propagated through horizontal gene transfer depends on the information of the transgene and the character of the gene construct. It must be assessed case by case for each herbicide-resistant plant.

5. When transgenes contain major sequences which are homologous to bacterial sequences and are coupled with promoters which also operate in bacteria, then a higher rate of horizontal gene transfer to soil bacteria must be expected than for natural (endogenous) plant genes. This applies, for example, to resistance to glufosinate (phosphinothricine) and to resistance to glyphosate induced by an *athrobacter* gene. Herbicide resistance genes isolated from bacteria or bacterial sequences (e.g. T-DNA) transferred together with resistance genes isolated from plants facilitate integration in the host genome. Promoters which operate in bacteria lead to the expression of the herbicide resistance genes and allow the selection of the transformed bacteria under the pressure of herbicide application.

6. On the other hand, even when herbicide resistance genes are isolated from bacteria, the transfer rate for them is not likely to be higher than for endogenous plant genes if they are coupled to a promoter which is only effective in

plants. Such constructs are feasible. Nor are increased transfer rates to be expected when herbicide resistance genes isolated from plants do not include bacterial sequences (this applies to glyphosate resistance induced by genes from maize or petunia).

7. When herbicide resistance genes have been isolated from soil bacteria then direct transfer between soil bacteria is much more probable than indirect transfer through the biomass from plants which have been genetically modified with such genes. This is, however, only the case if the herbicide resistance genes are from endogenous bacteria and, in fact, already abound in the soil where the transgenic plants are cultivated. For example, the bacteria which provided the gene for resistance to glufosinate (PAT gene) has not yet been demonstrated to exist in the soil of our region.

8. No increase in the rate of horizontal gene transfer is to be expected with transgenes conferring resistance against herbicides which specifically attack metabolic pathways in plants (this applies, for example, to bromoxynil). Such genes, even if they are occasionally picked up by bacteria, could not offer any selective advantage.

9. Since there are numerous strains of soil bacteria which carry natural resistance to nonselective herbicides, the use of these herbicides may by itself increase the probability that the resistance is propagated to other soil bacteria. However, the mechanisms involved in the natural resistance are still largely unknown. Thus, it is unclear how frequently the resistance is based on genes which can be passed on by transfer, or how frequently it is due to mutations. It is therefore not possible to estimate whether or not the rate of direct horizontal gene transfer from naturally resistant soil bacteria will be higher than the rate of transfer from transgenic plants.

(b) The probability of gene transfer to other plants

10. The horizontal transfer of herbicide resistance genes from transgenic plants to other plants is not impossible, but extremely unlikely. Theoretically, transgenes which are more likely to be transferred to soil organisms than natural plant genes are also more likely to be transferred back to other plants. However, the complete chain of the implied transfer events, each of which is relatively improbable, has an extremely low overall probability.

Question 2: What are the possible harmful effects of a horizontal gene transfer of herbicide resistance genes from transgenic plants?

Conclusions from the discussion

(a) Possible harmful effects of a transfer to soil bacteria

11. Horizontal gene transfer to soil bacteria will lead to the selection of a new herbicide-resistant bacterial population, when the herbicide is applied. If the emergence of this new population is not, in itself, regarded as a harmful effect, then only further consequences of it could constitute a harm. So far, however, all the consequences which have been identified or proposed already arise with conventional agricultural practice, quite independent of the introduction of transgenic crop plants. These consequences are neither specific to genetically modified plants, nor have they necessarily been regarded in the past as representing any damage.

12. One consequence of the selection of transformed, herbicide-resistant bacteria may be fluctuations or shifts in the composition and population dynamics of soil microorganisms. Such fluctuations or shifts are quite common anyway. Herbicide-resistant populations will grow whenever herbicides are applied—either due to the bactericidal side-effects of the herbicides, or due to the unavoidable selection of spontaneously resistant bacteria. In general, major changes in bacterial populations occur as a result of conventional farming practices such as ploughing, fertilising, or crop rotation.

13. The selection and growth of transformed, herbicide-resistant bacteria can lead to changes in soil chemical processes due to the release of metabolic substances not previously found in the soil. The same situation can also arise if new chemicals are introduced for crop protection, or if a crop species is cultivated which had not previously been grown in the area, or if a common plant variety is replaced by a new one.

14. It is conceivable that ”new” metabolic products which are introduced to the soil by transformed herbicide-resistant bacteria could disturb soil functions (e.g. soil respiration). This would no doubt constitute a harmful effect. However, such an effect is also conceivable with any other technique which influences chemical processes in the soil by introducing new substances or changing the quantitative relations of existing substances. It is much more probable that soil functions would be disturbed by the impact of herbicides directly, than by the impact of metabolic changes in bacteria expressing herbicide resistance genes which they picked up

from transgenic plants through horizontal transfer.

15. It is not possible to either confirm or refute the idea that the "new quality" implied in bacteria which have been transformed through horizontal gene transfer from transgenic herbicide-resistant plants will also involve some new form of harm. The transformed bacteria may bring metabolic products into the soil which are "new" in a different way than the new qualities which have up to now been brought in by known agricultural techniques. In theory, it is conceivable that they therefore have different effects than the known techniques. Although it may not be possible to describe these effects, nor to indicate a mechanism which explains how they could lead to appreciable damage, it is also not possible to exclude with certainty that they occur and could lead to damage in an unpredictable way.[27]

(b) Possible harmful effects of a transfer to other plants

16. In agricultural habitats horizontal transfer of herbicide resistance genes to weed plants could lead to the formation of new herbicide-resistant weeds when selective pressure through the respective herbicide is exerted. Consequently, the effectiveness of the nonselective herbicide would be diminished. However, resistant weeds are a common risk anyway; they are likely to emerge when the same herbicide is continuously applied, due to the selection of spontaneously resistant mutants. Horizontal gene transfer between plants, on the other hand, is extremely unlikely; it will, therefore, not be significant as a possible source of resistant weeds.

17. In natural habitats horizontal transfer of herbicide resistance genes to a wild plant genome would (under optimal conditions) give rise to nothing more than a single transformed herbicide-resistant plant within the wild population. It cannot be assumed that this plant could possibly outcompete its untransformed rivals in a natural habitat (i.e. without the selective pressure from herbicide applications) and become the origin of a new population.

[27] Whether assumptions of hypothetical risk warrant regulation, if they can neither be substantiated or theoretically refuted, was a major point in the normative discussions of the technology assessment, see section III C7 below.

3 Can feral populations of transgenic herbicide-resistant crops become obnoxious weeds or invade natural ecosystems?

Feral populations are formed when crop plants or their genes "escape" from cultivation and establish themselves outside their agricultural target sites. They may either become a weed in cultivated areas or invade natural ecosystems.[28]

There was agreement among the participants of the technology assessment that it is, in principle, to be expected that crop plants can escape from cultivation and form feral populations. The mechanisms through which this may happen—mainly hybridisation with related weeds or wild species—do, however, apply to transgenic and nontransgenic crops alike (in exactly the same way). Discussions in the technology assessment therefore concentrated primarily on whether it is reasonable to assume that transgenic crop plants will more easily lead to feral populations than plants produced by conventional breeding methods. In this connection it was also examined whether the cultivation of transgenic plants can legitimately be compared with the introduction of nonindigenous species. Such species are often ascribed a higher risk to escape because they are released from the natural ecological controls of the areas in which they have originally evolved. Critics of genetic engineering use the "exotic species model" to justify their assumption that transgenic plants pose a higher risk as well.

Another line of discussion considered the possible consequences of feral populations from transgenic herbicide-resistant crops. It was agreed that they could invade agricultural sites as (herbicide-resistant) weeds. This would aggravate the technical problems of weed management and possibly result in financial loss to the farmers. Doubts were raised, however, about whether herbicide-resistant plants would actually be able to invade natural communities and impair natural ecosystems. For the annual and biennial crop plants discussed in this technology assessment (in particular, sugar beet, potato, maize, and oilseed rape) such damage scenarios

[28] Expert report commissioned from Prof. H. Sukopp and U. Sukopp (Institut für Ökologie, Technische Universität Berlin): "Ökologische Langzeiteffekte der Verwilderung von Kulturpflanzen"; commentary by Prof. H. Scholz (Botanischer Garten, Berlin), in: *Materialien zur Technikfolgenabschätzung, Heft 4* (see appendix). Cf. also Sukopp and Sukopp (1993); Symposium (special issue of Molecular Ecology) (1994), Ammann *et al.* (1996), Keller *et al.* (1996).

were not regarded as realistic by most participants. The situation might be different, if competitive crops with a wide ecological range were considered (particularly woody perennials), or if properties were transferred which increase fitness (such as virus resistance) and give the plant a competitive advantage.

Other participants, however, insisted that feral populations from transgenic crop plants must in principle be expected to have a more serious ecological impact than feral populations from conventionally bred plants. They justify this assumption by pointing out that the genetic modification will have side-effects which might also influence the ecological behaviour of the engineered plant. Therefore, at least the uncertainty about its consequences must be greater than with conventional plants.

Question 1: Are transgenic crops more likely to escape from cultivation and form feral populations than conventionally bred crops?

Conclusions from the discussion

1. Generally speaking, it is to be expected that cultivated plants (i.e. plants which have acquired genetically fixed domestication traits as a result of breeding) can form feral populations; the plants may themselves escape from cultivation or propagate their genes through hybridisation to closely-related wild species.[29]

2. The probability that a feral population will be formed is low if the cultivated plant is highly domesticated and has no wild or weed relatives in the area where it is grown. These conditions are not, however, met in the case of every crop plant in Central Europe. There are a number of highly domesticated crop plants for which crossing partners exist in the wild flora of Central Europe. In addition, breeders also use less highly domesticated and even wild plants. Facultative cultigens (i.e. wild plants which are used as crops in agriculture just as they are) can usually spread spontaneously without restrictions. Therefore, the risk that a new crop could escape from cultivation and form a feral population varies considerably and must be assessed on a case-to-case basis.

3. The ecological behaviour of a plant has to be judged on the basis of its phenotype. When it comes to the question whether a crop which is herbicide-resistant is more likely to form feral populations than a nonresistant crop, it is irrelevant whether herbicide resistance has been acquired through conventional breeding, genetic engineering, or natural processes (mutations).

4. A genetically engineered crop only differs from the initial nontransgenic variety by a few genes. If the initial plant is native to the area where it is grown, then the same also applies for the transgenic variant. The fact that genes from organisms other than plants (e.g. from bacteria) may have been transferred, does not turn the transgenic plant into an organism which is nonnative in ecological terms. It is a mistake to consider transgenic crops as ”exotic species”. Plants do not evade the ecological controls which have evolved with them just because they are genetically engineered.

5. Data collected on the introduction and establishment of nonnative species can be used to infer quantitative statements about how likely it is in general that cultivated plants form feral populations and that these will have undesirable ecological effects. Such use of the so-called ”exotic species model” will, however, yield statements which apply equally for transgenic and nontransgenic crops. If a reference case is needed to assess the risks of a specific transgenic crop plant, then the only correct comparison is with the nontransgenic variety from which that plant has been derived. Moreover, even if the comparison of transgenics with exotic species is conceded, it does not necessarily support the conclusion that transgenics pose higher risks than nontransgenics. Nonnative crops may not be riskier than native ones since they frequently lack suitable partners for cross-fertilisation in their new environment.

6. Any form of developing a new crop variety, be it conventional breeding or genetic engineering, can lead to unexpected and unwanted changes in the phenotype of the plant, which run counter the breeder's plan. Such changes could possibly also increase the ecological range of the crop in question, and thus increase the probability that the plant (or its genes) become established in feral populations. Such changes are not, however, a specific risk of transgenic plants.

7. The claim made in the report of the Öko-Institut, that transgenic crops are in general more likely to escape from cultivation and form feral populations than nontransgenic crops, is based on hypotheses for which there are as yet no supporting evidence. Thus it is assumed that plants which have been genetically engineered are susceptible to more and wider-ranging unexpected phenotypic changes than plants which have been conventionally bred; or that

[29] The plant may also escape (without gene flow) by surviving over winter and appearing as a volunteer in the next crop.

transgenic crops are more likely to undergo evolution towards increased fitness. To justify these assumptions reference is made to the "special quality" of genetic engineering (in particular to disturbances of the genomic context and positional effects). This justification is invalid, however, if the postulated "special quality" of genetic engineering cannot in fact be substantiated.[30]

8. For the case-to-case examination of the risks which may be associated with the herbicide-resistant transgenic crops discussed in this technology assessment, the following conclusions can be drawn:

- For the cases of herbicide-resistant maize and potatoes, the risk that the plants (or their genes) escape from cultivation in Central Europe can be practically excluded. Both crops are highly domesticated, and there are no related species with which they could cross-fertilise among the Central European flora.
- In the case of herbicide-resistant sugar beet, the risks depend on where the beets are grown. In coastal areas hybridisation with wild beet is possible and has to be expected. Away from the coast, the development of feral populations is improbable.
- In the case of herbicide-resistant oilseed rape, there is a clear risk that the herbicide resistance is propagated. Spontaneous crossing occurs between a number of related cultivated species (*Brassica napus*, *Brassica rapa*, and *Brassica juncea*). Geneflow to closely related wild species is likely (in particular to *Brassica nigra* and *Sinapis arvensis*).

To date, research in ecological risk assessment seems to support the view that transgenic crops do not pose specific risks; they are not more likely to develop into feral populations solely because they have been genetically engineered. However, the results of this research may still be considered inconclusive, since the experiments have only been in progress for a few years.[31]

Question 2: Must we expect changes of natural ecosystems in case that transgenic herbicide-resistant plants (or their genes) escape from cultivation?

Conclusions from the discussion

9. The most common effect to be observed when crop plants (or their genes) escape from cultivation and become established in feral populations is the development of crop-weed complexes. Feral crop plants can invade agricultural habitats (fields, pasture) as weeds or spread to ecosystems which are highly disturbed by human activity (such as roadsides, wasteland, or industrial sites). As weeds they can lead to problems in land management and inflict financial losses on farmers (e.g. in terms of lower yields).

10. As far as the annual and biennial crop plants considered in this technology assessment are concerned, no effects on natural ecosystems resulting from invasions by feral populations (of nontransgenics) have been observed up to now. An exception to this is constituted by some hybrid forms of beets in coastal areas. In the case of transgenic herbicide-resistant crop plants, the transgene would not have any selective advantage outside areas where the respective herbicide is applied. So even if the transgene is dispersed to related wild species it would not enhance the ability of these species to invade natural ecosystems.[32]

11. On the other hand, it can also not be assumed that herbicide resistance genes which have been transmitted to a wild population through hybridisation will definitely disappear again from the gene pool of this population. The transgenes do not increase fitness, but neither do they necessarily involve fitness costs. Therefore some genes for herbicide resistance may become established in wild populations. This would, however, also be the case if herbicide resistance that has been acquired naturally (through mutation) or through conventional breeding was crossed out to related wild plants. There is no way to predict what the possible consequences of such genes in a long-term evolutionary perspective could be; any statement in this respect would be purely speculative.

[30] See section II A5 below.

[31] Mikkelsen *et al.* (1996) found hybrids of transgenic oilseed rape and weedy *Brassica campestris*; see also Jorgensen *et al*. (1996). The question is, how often do hybrids with wild relatives occur with nontransgenic rape varieties? Dale emphasises the need to investigate this to establish baseline data against which the possible impact of particular transgenes can be assessed (1994: 35).

[32] There may be some open questions as to whether the transfer of herbicide resistance could at the same time increase the resistance of the host plant to draught (Sandermann 1997: 215) or to cold (IHE 1994: 46).

4 Evolutionary aspects: Can transgenic plants change the course of natural evolution? Will they obstruct existing differentiation of species?

The Öko-Institut claims ”*evolutionary risks*” assuming that a massive release of transgenic herbicide-resistant crop plants could have negative effects on the biodiversity of natural species and communities in the very long term, i.e. over centuries or even millennia. The key mechanism for such effects is held to be the spread of transgenes to wild species, this amounts to a

> ”change of the parameters for future species formation.”[33]

On the other hand evolutionary risks are linked in various ways with a process of ”de-differentiation” which, according to the Öko-Institut, is involved in gene transfer between distant species: The transfer of bacterial genes to plants, for example, is seen as involving both a de-differentiation of the genome organisation of the transgenic plant and a de-differentiation of the existing species. The term ”de-differentiation” is meant to indicate a retrograde step or a loss in the structure or diversity which has been achieved through natural evolution up to now.[34]

The concept of ”evolutionary risk” is not common. Whether or not it can be defined clearly remained a moot point in the technology assessment. It was agreed that the effects transgenic crop plants might have on natural evolution in the distant future cannot be described or predicted in any way. Therefore, statements about such effects were regarded by some of the participants as completely futile. In addition, it remained unclear as to what extent possible influences on future processes of species formation should actually be counted as damage.[35]

Discussions in the technology assessment concentrated on whether it is at all possible to find a difference between transgenic and nontransgenic plants with respect to the effects such plants could conceivably have on natural evolution. Another point of discussion was whether gene transfer between distant gene pools could trigger the evolution of new species which would break through the reproductive barriers established by natural evolution. This discussion did not refer to claims made in the report by the Öko-Institut, but rather to speculation in the public discourse that genetic engineering could destroy natural distinctions between species.

Question 1: Should we expect that the release of transgenic herbicide-resistant crop plants will influence the evolution of species and natural communities in the distant future? Is it possible to distinguish effects transgenic plants might have from effects nontransgenic plants might have?

Conclusions from the discussion

1. The effects which the introduction of transgenic herbicide-resistant plants could possibly have on evolutionary processes in the future are unpredictable and indeterminate. The formation of new species, changes in the composition of plant communities, in the interaction between plants and other organisms, and in the structure of ecosystems are all conceivable and cannot, in any case, be excluded with certainty. Such effects are also conceivable, however, when new plants are introduced which have been modified using traditional breeding techniques.

2. It is questionable whether the chance that the introduction of new crop plants in agriculture might lead to the formation of new species in nature in the long run can be considered a ”risk”. In any event, such a ”risk” would not be specific to transgenic plants. As yet, there is no reason to assume that, in general, genetically engineered plants could more easily or more quickly induce evolutionary processes of species formation than conventional crops. There is also no reason to suppose that the evolution of a new species derived from transgenic crop plants is more likely to reduce biodiversity or disrupt the organisation of ecosystems than the evolution of a new species derived from nontransgenic crops.

3. Certain indicators for assessing possible evolutionary consequences of new crop plants can be inferred from the traits added to such plants, which would eventually escape to wild populations. In accordance with this, the possible consequences from herbicide-resistant plants should be negligible, since herbicide resistance is not an adaptive trait and provides no selective advantage in natural habitats. If, however, novel adaptive traits are added (resistance to draught or freezing, or improved photosynthesis, for example) then the effects could conceivably be greater, since such traits do represent a selective advantage.

4. This assessment holds irrespective of whether such novel traits are conferred through genetic

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[33] Weber (1994: 29/51/103). *Materialien zur Technikfolgenabschätzung, Heft 5* (see appendix).

[34] Weber (1994: 33/36).

[35] Cf. section III A2 below.

engineering or conventional breeding. The only mechanism for the escape of such traits from cultivation is cross-breeding with related wild species, and this mechanism propagates not only transgenes but also endogenous plant genes and the respective traits. (Horizontal gene transfer is not relevant for the gene flow from crop plants to wild species.) It is, on the other hand, true that phenotypes with novel traits transferred from nonrelated, distant species will, in many cases, only be possible through genetic engineering. Evolutionary consequences which might be associated with such phenotypes would then constitute a problem which is specific to transgenic plants. But even here, the fact that a phenotype is based on genetic engineering does not, as such, imply that the phenotype is dangerous in ecological or evolutionary terms. A case-by-case assessment is necessary.

5. The evolution of new species will have some influence on existing natural communities; the effect will depend on the phenotype of the species. It does not make sense to assume that every change which might be induced in a community necessarily represents a ”disruption”. In any case, the suspicion that transgenic species are, in general, more likely to give rise to ecological disruptions than nontransgenic species is unfounded. On the basis of our current knowledge, the potential damage new species can cause is probably limited. Taking as a comparison the long-term ecological impacts of invasions of crop plants into natural habitats, what could happen is that undesirable, ”weed-like” feral populations could be formed, which could jeopardise certain human uses of ecosystem functions, or could conflict with the goals of nature conservation by changing the regional spectrum of species. The idea that the spread of transgenics could lead in the long run to a disorganisation of ecosystems which would threaten the survival of humanity is mere speculation.

6. The statement that genetic engineering ”accelerates” evolution is confused. What is actually accelerated is the breeding process, i.e. the construction of crop plants adapted to and grown on agricultural land. Here genetic engineering makes combinations feasible which could not be achieved (or not as quickly) by conventional methods. Whether the possible impacts of these plants (or of their genes) on wild populations would actually ”accelerate” evolution in natural habitats is quite another matter.

7. Theoretically, every increase in genetic variability and every change in selective conditions can trigger evolutionary changes. In this sense, human activities ”accelerate” natural evolution mainly by changing the environmental conditions, in particular by extending anthropogenic locations, and by exploiting and polluting natural ecosystems.

Question 2: Is it conceivable that large-scale releases of genetically engineered organisms cancel naturally evolved differentiation between species and produce mixtures of species?

Conclusions form the discussion

8. When genes from widely different species are engineered into the genome of transgenic plants, this may be called, appropriately, ”de-differentiation”. In this case, the term would be used in a purely descriptive way, characterising the gene transfer as such, but not indicating any problem or loss associated with the transfer. The description would then also apply to certain crops that resulted from conventional breeding, for example, inter genera hybrids like triticale (a combination of rye and wheat).

9. However, the term ”de-differentiation” is not appropriate if it is used to convey that a problem is implied in genetic engineering, namely the loss of structure or diversity due to gene transfer. Such loss cannot be demonstrated, either at the level of the plant genome or at the level of the community of species.

10. At the level of the plant genome the inclusion of transgenes from other species does not represent a structural loss from the point of view of evolutionary biology, but rather, a gain. The genetic pool of the host plant population is expanded; genetic diversity (variation) within the species increases.

11. At the level of the species community there is a purely theoretical chance that the release of transgenic plants might initiate the evolution of new (transgenic or nontransgenic) plant species. If such species were to originate, they would possibly display combinations of traits hitherto excluded due to the reproductive separation of the species. Nevertheless, this would not constitute de-differentiation, but rather, differentiation of the spectrum of species. A new species does not replace the original species which contributed to their genome: it is added to them. On the level of the community the new species constitutes a gain in structure; its direct and primary effect is an increases in biodiversity.[36]

[36] It is quite another question whether the introduction of herbicide-resistant crops could lead to a loss of biodiversity in agricultural habitats, see section II C1 below.

12. The transfer of genes between different species does not lead to the disappearance of natural differences between these species. Although such fears have played a role in the public framing of the risks genetic engineering might involve, they are without basis in science. Species are defined as interbreeding communities (producing joint offspring). Gene transfer does not, however, create an interbreeding community between donor and host organism, and the transgenic does not become an ”intermediate” species between the original species. A transgenic potato with a herbicide resistance gene from a bacterium or a petunia will evidently continue to be a potato, and not a species half-way between a potato and a bacterium or petunia.

13. Transgenic plants which could be crossed with both the donor and the host organism are only conceivable in the case of gene transfer between relatively closely related plant species. Theoretically, in this case, an evolution might be possible during which the two originally separated species converge into a new ”intermediate” form. This would, however, only be possible, if one makes a further (improbable) assumption: namely, that this new form is fitter than the two original species and is able to outcompete them on a large scale. If one accepts this scenario for transgenic plants, then it must also be accepted as valid for the products of conventional breeding in which new varieties are produced by crossing related species.

14. In contrast to conventional breeding, genetic engineering can transfer genes between species which are widely different in evolutionary terms. However, the greater the evolutionary distance between the species, the lower the probability that they will somehow converge. Therefore, the further genetic engineering moves beyond the limits of traditional breeding, the less reason is there to fear that it could trigger evolutionary processes which end up in species mixtures and a loss of differentiation in the species spectrum.

5 The ”special quality” of genetic engineering

The strategic uses of ”context disturbances” and ”positional effects”

The argument that the insertion of transgenes will disrupt or disturb genomic contexts in the host organism and cause positional effects plays a prominent role in the criticism of genetic engineering in the report by the Öko-Institut and in the German discussion in general. It is seen as proof that the techniques of genetic engineering do indeed represent a novel or special quality which warrants the hypothesis that they might involve specific risks which do not occur when organisms are modified through traditional breeding techniques.

Risk debates in our technology assessment repeatedly ended up at a point where the conclusion seemed inevitable that it is not possible to distinguish the risks of transgenic plants from the risks of nontransgenic plants. Deliberations among the participants tended to ”normalise” risks by comparison.[37] Against this tendency the ”special quality” of genetic engineering was brought forward: Disturbances of the genomic context and the possibility of positional effects constitute a difference on the molecular level between genetically engineered and conventionally bred plants. Such differences therefore justify the assumption that the possible consequences of gene transfer are (in the words of a representative from the Öko-Institut)

> ”fundamentally different to what can happen with a nontransgenic plant.”[38]

In particular, the Öko-Institut referred to the ”special quality” of genetic engineering to justify the assumption of increased risks in the following cases:

- because of context disturbances and positional effects the genetic engineering of plants might involve more and different side-effects on the plant metabolism than are known from the history of conventional plant breeding;
- because of context disturbances and positional effects horizontal transfer of transgenes from plants to soil bacteria might have particularly serious and unexpected effects on the soil; the comparison, therefore, to agricultural practices which also severely affect soil may not be legitimate;
- because of context disturbances and positional effects transgenic crop plants might inadvertently achieve increased ecological fitness, thus enhancing their ability to invade agricultural or natural ecosystems as weeds.

There was agreement in the technology assessment that context disturbances (insertional

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[37] See sections III B1-2 below.

[38] Alternatively, the hypothesis that genetic engineering involves unique risks has been justified by reference to the fact that genes from distant, nonrelated species can be transferred which may inadvertently change the plant metabolism (see section II A1 above). According to this argument the constitutive difference is on the level of gene products, rather than on the level of molecular structure of the genome. However, both lines of argument converge in the conclusion that, because of the difference, more severe side-effects must be expected with transgenic plants than with conventional plants.

mutations) and positional effects do occur. Thus, the statement, ”It is the gene that matters!” which is part of the basic philosophy underlying common safety regulations, must indeed be qualified. The possible effects of gene transfer on the host organism cannot be derived completely from the information which is encoded in the transgene, nor from the function of the gene in the donor organism. To some extent these effects also depend on where and how the transgene becomes inserted in the genome of the host plant. In this sense, the statement ”It is the context that matters!” is also true.[39] There was, however, agreement in the technology assessment that the effects of changes in the genomic context are quite limited. They can influence levels of gene expression, but they cannot change the type of gene product which is added to the host organism (the possibility of fusion proteins being an exception).

Extensive discussions in the technology assessment concerned the question whether context disturbances and positional effects are in any way specific to genetic engineering and transgenic plants. Do they also occur in conventional plant breeding? What is the difference with natural recombination events, for example the insertion of mobile DNA elements (transposons), which take place in all plants anyhow? The debate of these questions in a way repeated the same arguments which had already ensued in discussion of the functional consequences of gene transfer. In both cases comparison with conventional breeding and natural processes was the test of whether genetic engineering is really new.

Question 1: Are disturbances in the genomic context caused by the insertion of transgenes (insertional mutations) comparable to disturbances which may occur, when plant genomes are modified through conventional breeding methods?

Conclusions from the discussion

1. Disturbances in the genomic context do not only occur when new genes are transferred through genetic engineering. A number of natural processes, e.g. chromosomal translocations during meiosis, and conventional breeding practices, such as intergenera crosses or chemical mutagenesis, also imply rearrangements in the context of the plant genome. The possibility of side-effects from such rearrangements is not specific to transgenic plants and thus is not sufficient to establish the ”special quality” of genetic engineering.

2. In the case of fusion proteins gene transfer leads to a new gene product which is not encoded in the transgene. Fusion proteins are formed when the transgene is incompletely integrated and its loose end happens to fall into the transcriptional frame of a neighbouring plant gene; then the transgene and the plant gene can together form a new gene product. Fusion proteins seem to be a good example that the genomic context (where and how a transgene is inserted) really matters. But again, fusion proteins are nothing which is specific to gene transfer; they can also result from conventional breeding processes which use chromosome breaks, translocations or mutagenesis as sources of genetic variation.

3. The hypothesis that changes in the genomic context by the insertion of transgenes could be different and hence have different consequences than changes which may be caused by conventional breeding techniques requires substantiation if it is to be more than mere speculation. The Öko-Institut has argued that there might be a ”gene balance” in the plant genome which is more likely to be disturbed by the insertion of transgenes than by modification through breeding techniques. It gives, however, no reason why such a balance, if it exists, should be less compatible with transgenes than with the various changes breeding can imply. The very fact that genetic engineering of plants is possible and successful seems rather to suggest that the integration of transgenes is compatible with the balance of plant genomes and the proper functioning of plants. It remains an open question whether more failures and nonviable variants are to be expected in the construction of transgenic plants than in conventional breeding.

4. Strictly speaking, it is also unwarranted to claim negatively that there are no differences between context effects in transgenic and non-transgenic plants. All what we can say is that no such differences can be recognised. Whatever we claim is valid only relative to the state of our current knowledge, and no level of knowledge will be sufficient either to prove that the suspected differences definitely do not exist or to exclude their possibility with certainty. This does not, of course, mean that we could just as well stop the systematic search for such differences—for example by comparing the effects of transgenes and transposons on the genomic context at identical gene locations (if the respec-

[39] The term ”context” refers to the molecular level of the genome in this section. It may also refer to the level of the gene product. The latter context, too matters as is demonstrated by pleiotropic effects. For the controversy over the appropriate ”safety philosophy” cf. section III B4 below.

tive experiments become feasible).

Question 2: Can changes in the genomic context which are caused by the insertion of transgenes be distinguished from changes caused by the insertion of transposons from the plant?

Conclusions from the discussion

5. Both transposons and transgenes interfere with the existing genomic context; the sequence of genes on the chromosome is altered in both cases.

6. To challenge the comparability of context effects from transgenes and transposons, it is not sufficient merely to cite any differences between transgenes and transposons. The differences must relate to the rearrangement of the genomic context. Various differences between transgenes and transposons have been claimed by the Öko-Institut; only two of them relate to the genomic context: the reversibility of transposon insertion and the regulation of the insertion site by the plant itself.

7. The following differences have no relation to possible changes in the genomic context:
- *The number of plants.* Given the large-scale cultivation of transgenic crops, plants with context effects from the insertion of transgenes may be much more frequent than plants with context effects from the insertion of transposons. This does not mean that the effects are different in both cases or have different consequences for the plant. Furthermore, new plant varieties which are based on transpositions could also be grown in large fields.
- *The content of genetic information.* Transposons can, like transgenes, add new phenotypic traits to the plant; but only transgenes can transmit genetic information which has never been in the plant gene pool from nonrelated organisms. The content of the genetic information is relevant for the gene product and its consequences. It does not, however, determine the effect of the transfer on the genomic context.
- *The frequency of transposition.* The frequency is regulated by the plant. This suggests that transposons have a definite function in the developmental programme of the plant. Frequency has no implications for how the insertion of transposons will change the genomic context. This change depends on the site in the genome to which the transposon moves, not on the frequency with which it moves.

8. Gene transfer aims at the stable integration of a transgene into the plant genome. For transposons it is, in contrast, quite normal that they frequently and spontaneously move out of the gene locus into which they have jumped. Transposition is reversible. This does not mean that its effects on the genome organisation are negligible. Transposons which move out not only leave behind changes in the place where they have been, but they also induce further changes in the place to which they jump. If the frequency of insertions indicates the amount of side-effects involved, then more side-effects have to be expected from a transposon than from a transgene.

9. The real test whether context changes through transgenes and through transposons are comparable lies in what determines the locus of insertion. Genetic engineering cannot yet control the exact locus on the host genome to which a new gene is transferred. Transgenes are inserted at random. If the gene locus at which transposons are inserted were regulated by the plant itself, then transpositions would indeed be different. There is, however, no evidence for such regulation. Transposons are also inserted at random. This is the current state of our knowledge, and there is no controversy in science over this fact.

10. Data suggest that there are similarities between the transposons and the gene sequences at the locus at which they integrate. It would be a misinterpretation to conclude from such data that the insertion of transposons is regulated by the plant. If for chemical and physical reasons certain sites on the genome lend themselves more for the insertion of transposons than others, then the distribution of transposons over the genome would not, in fact, be completely at random. Nevertheless, it would not be controlled by a regulatory programme of the plant itself. And, such deviances from random distribution could then also be expected for the integration of transgenes.

11. As a general comment to the whole debate it can be added that transposons are but one example of random processes in plants which influence the genomic context. One could also point to mutations which insert or delete genetic information. These mutations also refute the thesis that disturbances in the genomic context are a unique and specific risk factor of genetic engineering. In the final analysis it seems difficult to uphold this thesis in view of the fact that natural evolution presupposes random change in genomic contexts. It is unlikely that a ”special quality” of gene transfer can be established at the level of organisation of the genome; one will have to look for it at the level of the gene product.

B BIOSAFETY ASPECTS OF NONSELECTIVE HERBICIDES

With the construction of transgenic herbicide-resistant plants, broad spectrum, nonselective herbicides (which normally affect all or nearly all plants) can be used widely in agriculture for the first time. This raises further issues of biosafety for such plants: What risks are involved in the use of nonselective herbicides, both with respect to the consumers' health and to the integrity of the environment?

These risks are examined extensively within the established procedures for approval before nonselective herbicides can be placed on the market for agricultural application. They are nevertheless critical points of public debate.

In our technology assessment, the biosafety aspects of nonselective herbicides were discussed mostly in a comparative way: Do these herbicides change the present situation to the better or to the worse? A number of participants continued to argue, however, that these herbicides would still be unacceptable even if they did improve the status quo. This group considered any use of herbicides unacceptable.[40]

It was agreed that the question whether the amounts of herbicides applied in agriculture would increase or decrease once transgenic herbicide-resistant crops were introduced, is a key issue for assessing the impacts of nonselective herbicides, not only with respect to possible risks, but also with respect to possible benefits and changes in agricultural practice. Our summary, therefore, starts with the discussion of this issue.

1 Will greater or lesser amounts of herbicides be applied when transgenic herbicide-resistant plants are grown?

Opinions are divided over this question. Whereas critics of herbicide-resistant crops warn that farmers will use more herbicides than they have up to now, supporters of the technology claim, to the contrary, that farmers will use significantly smaller amounts of herbicides.[41]

This debate proceeds from the assumption that the amount of herbicide used is a good indicator of whether the burden on human health and environmental integrity is likely to increase or to decrease. This assumption was also made in the technology assessment, but it was agreed that comparing quantities is only a very crude indicator for comparing the possible negative impacts of herbicides. What would really be needed would be a comprehensive index integrating the amount of herbicides applied and the parameters of toxicity and, in addition, taking into account local conditions at the place of application (e.g. type of soil, susceptibility to erosion etc.). It has not been possible to develop such an index.[42] Thus, comparing amounts of herbicides is a substitute which will only provide relevant information if the nonselective herbicides used in conjunction with transgenic plants and the selective herbicides used with conventional plants are widely similar in terms of their toxicity and ecotoxicity. This can be taken as being the case for glyphosate (Round-up) and glufosinate (Basta), the main herbicides considered in this technology assessment.

Arguments about the development of herbicide use often imply that transgenic herbicide-resistant crops could become standard for most areas of agricultural cultivation. As a matter of fact, nonselective herbicides would probably not be applied in all crops. The most likely candidates are row crops. Cereals, in contrast, are often competitive enough and may not need herbicide treatment at all; and, if necessary, conventional weed control methods are available (including selective herbicides) which are both effective and cheap. As a result, one quarter of the total cultivated land might well be the maximum range of application for nonselective herbicides.[43]

Discussions of whether greater or lesser amounts of herbicides would be used must differentiate between the various crop cultures and answer two questions: Will the amount of herbicides used per hectare increase or decrease? Will the total agricultural area treated with

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[40] Cf. section III C3 below.

[41] In our technology assessment, discussions of the issue were based on several expert reports and commentaries dealing with agronomic and economic impacts of herbicide-resistant crop plants; see section II C below. For a more comprehensive account of the discussion in the technology assessment see: "Entwicklung der Aufwandmengen beim Herbizideinsatz", in: *Materialien zur Technikfolgenabschätzung, Heft 6: 126-152* (see appendix).

[42] According to a Danish expert the problem is: "how to compare LD50 values with e.g. the persistence. You have to put some value judgement into each of those parameters. That's why it is very difficult to reach any agreement on it" (IHE 1994: 49).

[43] While this may be the case in Central Europe Gressel (1996: 240) sees a definite need to engineer new herbicide resistances into wheat in order to control grass weeds in India, for instance.

herbicides increase or decrease? In our technology assessment, comparisons were generally made with the weed control strategies farmers normally apply at present. For most crops this means application of selective herbicides, but for some crops, also mechanical methods. A great deal of discussion was devoted to the question of whether herbicide-resistant crops would ”invite” farmers to use herbicides excessively, since they must no longer fear that they might damage their crops. If this were the case, then reductions which might be possible in theory would not be realised in practice. Three main topics turned out to be relevant in the discussions of the technology assessment:

- the technical options herbicide-resistant plants may involve for reducing the amounts of herbicide applied in various crops,
- the level of herbicide management that would be required if these options were to be realised in actual practice
- the displacement of mechanical methods of weed control by nonselective herbicides when herbicide-resistant crop varieties become available.

The following conclusions from the discussions must be viewed as preliminary. Herbicide-resistant crops have not been widely tested under practical conditions. Therefore, neither the effectiveness of nonselective herbicides nor the details of their regime of application are yet completely clear.[44]

Question 1: Will the use of herbicide-resistant crop plants lead to reductions in the amounts of herbicide applied?

Conclusions from the discussion

1. Herbicide-resistant plants favour the switch to postemergence treatment in weed control, where the farmer can wait until the weed grows and then decide whether or not treatment is necessary. Nonselective herbicides such as glyphosate (Round-up) or glufosinate (Basta) are better in this respect than the (selective) postemergence herbicides which are available at present. They imply less damage to the crop plants and have a more complete spectrum of weed control. Whether the switch to postemergence treatment will in fact reduce the amount of herbicides used depends on the exact scheme of herbicide application.

2. In theory, nonselective herbicides could be applied at a very late stage in plant growth. However, such application is not likely to become a standard method of weed treatment. Since weeds would also be larger at this stage, they would compete more vigorously with crops; they are also a source of viruses which damage crops. In either case, yield losses must be expected if weed control is postponed for too long. For agronomic reasons it will, therefore, probably only be possible to delay herbicide applications by up to about 14 days beyond the usual date.

3. With glyphosate (Round-up) and glufosinate (Basta) current experience suggests that the best scheme of application might be to split the treatment: A crop would then be treated the first time at about the four-leaf stage, when the first wave of weeds has appeared in the field. A second treatment is envisaged at about the ten-leaf stage, when weeds have emerged again. Second (and further) treatments may eventually be spared if the pressure from weeds is low and the crop sufficiently competitive.

4. Calculations have been made for the various crops, which suggest that with nonselective herbicides (in particular glyphosate and glufosinate) some reductions in herbicide quantities might be achieved for various crops. Expected reductions are considerable for sugar beet—up to 30%. No reductions can be expected for cereals, if herbicide-resistant varieties are not developed because they are not economically attractive. In cases where the fields are infested with weeds which are particularly hard to control using conventional (selective) herbicides, significant reductions can be expected for all crops.

5. These calculations are contingent upon two assumptions: (a) that the doses necessary for effective weed treatment are less with nonselective than with selective herbicides; this would be true particularly in the case of strong weeds which must be treated with high doses and combinations (tank mixtures) of selective herbicides; (b) that the number of applications per year can be reduced in some crops; further applications in a splitting scheme could, for example, be spared if the re-emerging weeds are too weak to compete with the crop plants.

6. Whether herbicide reductions which are possible in theory can actually be achieved in practice will have to be tested in further field trials.[45]

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[44] Data have only recently become available; see Reschke (1996), and Rasche, Donn and Waitz (1996); we quote from these data in subsequent footnotes.

[45] Recent trials with glufosinate resistant sugar beets suggest that 4-6 litres of the product per hectare (in two applications) provide sufficient weed control; this compares with 8-9 litres of selective herbicides used at

7. Should the use of broad spectrum herbicides lead to the selection of resistant weeds, farmers might try to maintain effective treatment by increasing the doses of herbicides applied. Any reductions vis-à-vis the status quo that might have been achieved with nonselective herbicides, would in this case be negated. Theoretically, the amount of herbicide used could even be increased for a while, until it is clear that the herbicide is no longer effective.[46]

8. It is sometimes argued that herbicide-resistant crops will result in increased overall amounts of chemicals used in agriculture, assuming that transgenic varieties will be less competitive or particularly susceptible to fungal attack (therefore requiring more fertilisers or fungicides). These assumptions seem to be unwarranted: If transgenic crops had lower yields or required more fungicides, they would fail to establish themselves on the market.[47]

Question 2: Will herbicide-resistant plants increase the amount of herbicides applied in agriculture because they are more likely to be misused?

Conclusions from the discussion

9. Proper herbicide management requires more than just adhering to the maximum doses permitted for the product applied. For reasons of product liability, the permitted doses are set at high levels which, even under unfavourable circumstances, guarantee effective weed control. In practice, lower doses are often possible and indeed advisable. If integrated crop protection and good field practice are the criteria, then normal herbicide management in Germany displays many shortcomings, including unnecessary routine applications of herbicides, excessive dosage locally, and lack of herbicide rotation. Many cases of groundwater pollution and the selection of resistant weeds can be ascribed to inadequate herbicide management.

10. Because of pressure from rising costs, farmers have a clear economic incentive to manage herbicides properly and reduce the amounts of herbicides they invest. This is, of course, only true if herbicides represent a relevant cost factor. In this respect, atrazine is an exceptional (low cost) case. In general, the prices of herbicides are such that farmers will try to profit by using less of them. This is borne out by the fact that the turnover for herbicides has fallen dramatically in recent years.

11. Deficits in herbicide management are a general problem; nonselective herbicides will be no exception in this respect. However, there is little reason to suspect that nonselective herbicides would be handled particularly recklessly because crops are resistant, or that the farmers would engage in more unnecessary treatments or use excessively high doses. This could only be expected if economic controls played no role with nonselective herbicides, which is clearly not the case.

12. Nonselective herbicides like glyphosate (Round-up) and glufosinate (Basta) could, on the contrary, resolve a number of management problems which up to now have led to increased uses of herbicides. The incomplete spectrum of traditional herbicides causes problems in major crops: Weeds are selected which are particularly difficult to control and require additional herbicide use. The selection of such weeds could be avoided with broad spectrum, nonselective herbicides. Some of the herbicides to be used with transgenic herbicide-resistant crops may come close to meeting the standard of completed weed control.[48]

Question 3: Will nonselective herbicides displace mechanical methods of weed control?

Conclusions from the discussion

13. Mechanical weed control has already largely been displaced by herbicide application over the

present (Reschke, 1996). For the agronomic details, see below, section II C2 below. With oilseed rape, one application of up to 600 g active ingredient is enough (Rasche *et al*., 1996). This does not necessarily constitute appreciable reductions compared to current practices; see also IHE (1995: 4). With glyphosate-resistant sugar beet two applications of two to three litres per hectare provide sufficient control. Reductions might be considerable in crops not dealt with in our technology assessment, for example, cotton. "In fields with light infestations of weeds, producers should be able to use total postemergence management systems. The herbicide load in theses fields could be reduced by at least 50% as compared to current management systems" (Wilcut *et al*. 1996: 221).

[46] The risk that resistant weeds are selected depends on the mode of action of the herbicide resistance. The risk appears low in the cases of glyphosate (Round-up) and glufosinate (Basta), and it is assumed that it can be kept within limits for all nonselective herbicides by proper herbicide management (e.g. herbicide rotation), see section II C2 below.

[47] Ahmad *et al.* (1995) did find that glufosinate impairs the antagonistic control of the phytopathogen *Fusarium oxysporum* by *Trichoderma* species. However, this does not, according to information from AgrEvo, result in increased need of fungicides. See, however Gressel (1996: 243) "Even low rates of glyphosate suppress the production of induced phytoalaxins that defend against fungal attack".

[48] Although glyphosate and glufosinate, too, have gaps in their weed control spectra. Cf. section II C2 below.

recent decades. It is now restricted mainly to organic farming and to areas in which available herbicides are inapplicable because of incomplete control spectra or adverse environmental impacts. Mechanical methods of weed control are also given some weight within integrated crop protection schemes. One must expect that when nonselective herbicides with sufficient control spectra or favourable environmental properties become an available alternative, they are likely to encourage further displacement of mechanical weed control methods in conventional farming because they are labour-saving and more cost-effective.

14. The potential of mechanical weed control methods has not yet been fully exploited. Mechanical methods can, for example, be quite cost-effective in cereal crops with a low incidence of weeds. In such crops mechanical methods may even be indirectly supported by the introduction of herbicide-resistant plants. If broad spectrum, nonselective herbicides are applied in a postemergence treatment of row crops, they will also reduce weed pressure on cereals which are grown the following year; mechanical treatment might then become technically and economically viable. This effect could be very wide-ranging, since cereals account for some 75% of the cultivated land in Germany, and since about half of them are cultivated after row crops which are the main targets of transgenic herbicide resistance.

15. To the extent that nonselective herbicides displace mechanical weed control, the introduction of transgenic herbicide-resistant plants will increase the use of herbicides in agriculture. The effect will be rather limited, however, because mechanical methods are already very marginalised in conventional farming. The various crops have to be considered case by case.

16. For potatoes, which are grown on about 4% of Germany’s farmland, mechanical weed control will continue to be practised where it can be integrated with other agronomic measures, like hoeing or hilling up, both of which are necessary for cultivation of the crop. Mechanical methods might be displaced, however, in areas where (preemergence) treatment with traditional herbicides was inappropriate because these herbicides did not meet water protection standards or because they did not have a sufficient spectrum of control. In those cases, the availability of applicable nonselective herbicides could result in increased amounts of herbicides used in potatoes.

17. On the other hand, this negative effect might be compensated, if the number of herbicide applications could be reduced by shifting to postemergence treatment in conjunction with herbicide-resistant potatoes. Preemergence treatment, which is a routine in many areas, could then be abolished and the farmer could instead decide on the spot whether the actual weed pressure warrants any further herbicide application, or whether the mechanical measures they use anyway are sufficient to cope with the problem. It is not possible to predict whether the net effect of these contradictory developments would be a rise or fall in the amount of herbicides used for cultivating potatoes. The effect is, at any rate, not likely to be appreciable.

18. Even if nonselective herbicides replace mechanical methods of weed control for some crops, this does not imply that they result in increased overall use of herbicides in agriculture at large. The areas in conventional farming where mechanical methods of weed control are used are minimal in comparison to those areas where herbicides are applied. And, in the latter case, the applicability of nonselective herbicides will probably lead to a reduction rather than increase in the amounts of herbicides used.[49]

2 Impacts on health: residues from nonselective herbicides in food crops

Only transgenic herbicide-resistant plants can be exposed to nonselective herbicides without being killed. Obviously, therefore, products from such plants may have residues that are different from those which could occur in products from non-transgenic plants exposed to selective herbicides. The decisive point here is not that the herbicide resistance has been genetically engineered, but that a new herbicide is applied. A new situation with respect to residues would also arise if resistance to nonselective herbicides was created with other methods (e.g. through conventional breeding) or if crops were exposed to newly developed selective herbicides which make use of a natural tolerance mechanism, the operation of which implies that the herbicide will have some impact on the plant metabolism.

[49] The displacement of mechanical methods of weed control may nevertheless be an undesirable political signal. Even participants in the technology assessment, who did not oppose herbicides in principle argued that technical monostructures in weed control and over-reliance on chemical methods should be avoided (see section III F3 below). Mechanical methods of weed control should therefore continue to be applied and innovated. However, this goal cannot be pursued successfully by restricting herbicide-resistant crops; financial support for the mechanical methods is what is required.

Existing law requires that a toxicological dossier of residues which could occur in transgenic herbicide-resistant crops be produced before nonselective herbicides can be approved for application to such crops. It can be assumed, therefore, that these herbicides would not be released onto the market were they to lead to toxicologically incompatible residues in food products. A technology assessment can neither substitute nor anticipate the extensive testing that precedes the approval of new herbicides. It can only raise points which should be considered in the testing. On the other hand, it can go beyond the criteria which are already legally binding. Some participants in our technology assessment argued that the criteria for herbicide approval should become stricter; they also debated whether the existing rules are applicable and appropriate for nonselective herbicides.

There was agreement that it would be undesirable and a clear disadvantage of transgenic herbicide-resistant plants if nonselective herbicides involved higher residues in crops. This opinion was held irrespective of whether or not the residues remained within the limits of what is tolerated under the usual toxicological criteria. More residues in food crops were regarded in principle as undesirable. However, no agreement was reached about whether the residues would actually increase or decrease. It was clear that this would depend on the mode of action of herbicide resistance, on the timing of herbicide application (early or late postemergence treatment and harvest delay), and on an increase or decrease in the amount of herbicides applied per hectare.

Apart from this question, it was also discussed whether our current state of knowledge was a sufficient basis for testing the residues of nonselective herbicides and controlling possible risks for the consumers. A number of participants denied this and concluded, therefore, that these herbicides could not be approved at all.[50]

[50] Expert report commissioned from Prof. H. Sandermann (Forschungszentrum für Umwelt und Gesundheit, Neuherberg) and Prof. K.-F. Ohnesorge (Institut für Toxikologie, Universität Düsseldorf): "Nutzpflanzen mit künstlicher Herbizidresistenz: Verbessert sich die Rückstandssituation? Biochemische und toxikologische Aspekte"; commentaries from environmental groups by V. Haas and L. Peters (Umwelt-Institut München); W. Bödecker, (Pestizid Aktions Netzwerk, Hamburg), commentary from industry by J. Honegger (Monsanto), in: *Materialien zur Technikfolgenabschätzung, Heft 6* (see appendix).

Question 1: Will the application of nonselective herbicides lead to increased residues in the harvested crop plants?

Conclusions from the discussion

1. For herbicide-resistant plants the amount of herbicides applied per hectare and year will probably be somewhat reduced in comparison to those currently in use; with certain crops, for example, sugar beet, these reductions may be considerable. This suggests further that the situation concerning herbicide residues should improve rather than worsen with the introduction of herbicide-resistant plants. In general, when less herbicides are applied, less residues must be expected in crops.

2. Herbicide residues are likely to increase in those crops where nonselective herbicides displace mechanical weed control. Ironically, this could also be the case exactly because these herbicides are better in environmental terms. For example, should they be classified as not harmful to water, they could be used in protected areas where conventional herbicides were inapplicable. Displacement can only affect a small percentage of farmland, however, since mechanical weed control is already highly marginalised in the present system of crop husbandry.

3. On the other hand, residues are likely to decrease where nonselective herbicides allow a reduction in the total number of herbicide treatments in a yearly crop sequence. If herbicides lower weed pressure by reducing the seed bank, then successive treatments in the following crop may become unnecessary. This could, for instance, be the case with cereal crops which can compete well with weeds; at present these crops are still widely treated with preemergence herbicides.

4. The shift of herbicide application to postemergence treatment does not necessarily imply increased residues. Presumably, nonselective herbicides would not be applied at a very late stage of plant growth, but rather in a scheme of split applications relatively soon after the weeds first appear in the field. This ensures sufficient delay of harvest and, therefore, time for herbicide residues to be diluted in the crop.

5. Increased residues could result if farmers resort to herbicide application at later stages of plant maturity shortly before harvest, in the case of unexpected and unusually high weed pressure. Such applications are more likely to occur with nonselective than with conventional postemergence herbicides, since the former are less likely to affect the crop and cause yield losses. Therefore, very late additional treatment could

prove profitable. It may be necessary to restrict such applications of nonselective herbicides by regulation, in order to ensure that residue concentrations would be reduced sufficiently by plant growth and plant metabolism, so that tolerances of residues are not exceeded in the harvested crop.

6. Herbicides can nevertheless be abused and thus give rise to additional residues. For instance, a farmer, if confronted with unforeseen weed problems, may disregard the rules of herbicide approval and good field practice, and use nonselective herbicides anew, shortly before harvest. Such abuse is, however, a general risk with postemergence herbicides; with all of them, late applications which have neither been tested nor authorised remain technically possible.

Question 2: Do we have sufficient knowledge to assess possible residues from nonselective herbicides and to control toxicological risks for the consumers?

Conclusions for the discussion

7. Many of the arguments that the necessary knowledge is not available refer to points which have to be considered in the tests legally required before approval is granted for use of nonselective herbicides in conjunction with transgenic herbicide-resistant crops. It can be taken for granted, therefore, that the accumulation of active ingredients in a crop or the degradation pathways of nonselective herbicides in plants will be investigated, and that residues will be subjected to standard toxicological testing and evaluation. This also includes metabolites of the herbicides, formed only in plants, if it is possible to extract them.

8. The tests developed for the approval of herbicides have systematic limits for methodological and technical reasons. What cannot be known cannot be tested. There is, for example, no way to test whether herbicide residues at concentrations below the level of detection exist and, if so, whether they might be toxicologically relevant. There is also no definite answer as to how reliable extrapolations from animal testing to humans really are. Furthermore, metabolites of herbicides which are only formed in plants cannot, as a rule, be tested if they remain undetected, or if they cannot be isolated from the plant itself. Feeding the crop to animals would be one theoretically possible test strategy; but in practice this is often impossible because the amount of plant material needed to produce base-line effects for toxicological assessment cannot be incorporated in the test animals without killing them.

9. The testing of herbicides is also limited for pragmatic reasons. In general, a toxicological dossier related to health risks is confined to the active ingredients in herbicides. The formulation, i.e. additional substances required for application in the field, is tested only if evidence suggests that it might involve risks. Moreover, the number of model systems (animal species) tested is limited in order to keep the costs of testing within acceptable bounds. Tests for synergistic effects are not carried out systematically, but only when there is specific evidence of toxicologically relevant interaction.

10. Despite these limitations there is no empirical evidence that existing herbicide regulation fails to protect consumers against health damage from herbicide residues. Levels of residues are routinely controlled in samples of food products. Violations of maximum permissible levels rarely occur; usually the quantities of residues are well below this. Nor are there any epidemiological data suggesting that herbicide residues in harvested crops constitute health risks (in contrast, for example, to chemicals used in wood protection or medical drugs). Cases of poisoning have been recorded for individuals handling herbicides during application, or manufacturing, but not for consumers ingesting food products from crops treated with herbicides (although herbicides—paraquat, for example—have, been deliberately ingested to commit suicide).

11. Regulations for the approval of herbicides involve political compromise, since they try to strike a balance between maximising the prevention of risk and allowing for innovation of weed control techniques. Any such compromise is likely to remain controversial in the public realm, and it also remained controversial in our technology assessment. This is perhaps not surprising in view of fundamental disagreement about whether chemical crop protection is acceptable at all in agriculture. When any use of herbicides is rejected as a severe mistake, one cannot, of course, be satisfied to learn that nonselective herbicides pose no special problems in comparison with conventional (selective) ones.[51]

3 Impacts on the environment: Are nonselective herbicides more environmentally friendly?

Our technology assessment examined the possible effects of nonselective herbicides on soil (including problems of soil erosion), on aquatic ecosystems and on the phytocoenosis in agri-

[51] For this debate see section III C3 below.

cultural habitats. The findings tended to emphasise that the proper use of nonselective herbicides would at least not aggravate the environmental impacts of current herbicide applications in agriculture, but that the improvements to be expected would probably also be only slight. Improvements were projected from favourable soil and ecotoxicological properties of some nonselective herbicides, and from the assumption that theoretically possible reductions in application rates and numbers of treatments would be actually achieved in practice.

For the critics of herbicide-resistant crops these findings, while not contested in principle, nevertheless did not warrant the conclusion that nonselective herbicides pose no particular environmental problems. They argued that the current state of knowledge does not allow us to predict all the possible effects and that tests conducted for herbicide approval cannot definitely exclude the possibility that additional risks might nevertheless exist. The other participants acknowledged these points but countered that they merely describe general problems which apply to any scheme of risk testing and risk regulation. The question of whether limits of knowledge and preventive control are sufficient to deem a new technology unacceptable remained one of the controversial issues of legal and political debate in the technology assessment.[52]

As in the discussion of health impacts, the critics did not accept the comparison of selective and nonselective herbicides when assessing environmental impacts. They insisted that organic farming was the only appropriate system of reference and alternative to be considered. This argument also reflected the basic differences in value judgements among participants in our technology assessment.

Question 1: Have nonselective herbicides less effects on the soil than herbicides which have been used up to now?

Conclusions from the discussion[53]

1. The nonselective herbicides to be applied with transgenic herbicide-resistant crops differ little in terms of their effects on the soil from the herbicides already used. In certain respects, for instance, rapid degradation (persistence) and low soil mobility (bonding and leaching), they are slightly better.[54]

2. If it turns out that lesser amounts of herbicides will be used with transgenic herbicide-resistant crops then, in principle, the burden on the soil will decline. Whether this effect is actually significant remains to be established in field trials.

3. Predictive testing of soil behaviour faces methodological problems. Tests are not carried out in the field, but in the laboratory on standardised model soils which do not adequately reflect the complexities of the processes in real soils. The results must be extrapolated from the model systems to the agricultural fields. Such extrapolations are only valid to a limited extent.

4. Synergistic effects which might arise from interaction between nonselective herbicides and soil substances and metabolic products formed by soil microorganisms under pressure from herbicides are not explicitly tested. They are, however, dealt with implicitly through tests for possible negative impacts on soil functions like respiration.

5. The methodology and theory of soil testing performed with nonselective herbicides reflect the state of the art in soil science. Current knowledge may be unsatisfactory and, therefore, predictions of effects on real soil processes fraught with significant uncertainty. Such uncertainty will then, however, not be confined to the assessment of nonselective herbicides: it will apply likewise to possible soil impacts from new selective herbicides and other agronomic changes like new tillage schemes, variations in fertilisation, or variations in crop rotation. In general, the limits of predictive testing are a problem for all precautionary regulation of new technology. If such limits are not sufficient to ban a technology outright, then they must be compensated by monitoring the technology after it has been introduced.[55]

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[52] See section III B7 below. The issues are the same for conceivable risks from transgenic plants and nonselective herbicides.

[53] Expert report commissioned from Prof. B.-M. Wilke (Institut für Landschaftsbau, Technische Universität, Berlin): ”Verhalten der Komplementärherbizide im Boden”; commentary by Dr. Ch. Siewert (Institut für Ökologie [Bodenkunde], Technische Universität, Berlin), in: *Materialien zur Technikfolgenabschätzung, Heft 7* (see appendix).

[54] See also Moorman and Keller (1996).

[55] This solution was favoured by the majority of participants in our technology assessment, see section III E2 below.

Question 2: Will the application of nonselective herbicides have an effect on soil erosion?[56]

Conclusions from the discussions

6. The use of herbicides is not a major factor of soil erosion in agriculture. Soil erosion is mainly due to mismanagement with respect to tillage and site-specific choice of crops to be grown.

7. Theoretical calculations predict a certain reduction of the disposition to soil erosion when nonselective herbicides are applied in postemergence treatment of weeds. The underlying assumption is that the soil will be better and, for a longer period, covered by weeds (or their remains after treatment). Reductions will vary depending on location, choice of crop and modalities of herbicide application. The calculations suggest, for example, that the disposition to erosion may be reduced by 11% for sugar beet and 7% for potatoes and oilseed rape if nonselective herbicides are applied to one crop in the rotation sequence. If they are applied to monocultures of corn the factor may be as high as 17%.

8. Positive effects on soil erosion calculated for the case of late postemergence applications will not be achieved if nonselective herbicides are applied in repeated treatments of low dosage (splitting). Whether in this case a clean weeding effect results, which would actually increase the disposition for soil erosion, remains to be seen. Theoretically, a certain negative effect is plausible. This effect does not occur, if combinations of selective herbicides (tank mixtures) have been used up to now, which also lead to broad spectrum weed control; in any case the impact would be quantitatively small.

9. The predicted changes in the disposition to soil erosion are derived from model calculations which disregard the high fluctuations of natural events. It is, therefore, questionable whether they could be demonstrated in real practice. They are in any case significantly smaller than changes due to normal practices in agriculture, like variations in crop rotation or tillage techniques. Any positive effect the application of nonselective herbicides might have for soil protection is negligible compared to the improvements that would be achieved through proper, site-specific agronomic management.

10. In theory, transgenic herbicide-resistant crops offer new opportunities to shift to techniques of conservation tillage and mulch cropping, which imply significant improvement in soil protection against erosion. In practice, however, a major shift is not likely to occur within our present system of agriculture, because it depends on economic profit rather than on technical opportunity.[57]

Question 3: Will water pollution levels be reduced when nonselective herbicides are applied in conjunction with transgenic herbicide-resistant crops?[58]

Conclusions from the discussion:

11. The pollution of groundwater with residues from herbicides is due partly to the properties of the herbicides themselves and partly to poor management or reckless handling in herbicide application and disposal. Nonselective herbicides with favourable properties (low mobility and rapid degradation in the soil) may reduce the risk of groundwater pollution. Whether they would actually improve the situation measurably, as long as the practice of herbicide handling is not effectively controlled, remains an open question.

12. One must expect that herbicides used in agriculture will leach into surface waters, since some soil loss and run-off from farmland is inevitable. Leaching may be slightly lower with nonselective herbicides, such as glufosinate or glyphosate, than with the selective herbicides conventionally used. This projection is based on the assumption that the amounts of herbicides will be reduced as calculated. A countervailing factor might be that herbicide washout from crop leaf surfaces could increase if postemergence, contact herbicides are applied. It is not to be expected, however, that this factor would completely outweigh the advantages from a reduction in the amounts of herbicides used.

13. A possible ecological risk is that herbicides leaching into surface waters could induce the

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[56] Expert report commissioned from Prof. K. Auerswald (Institut für Bodenkunde, Technische Universität München): "Auswirkungen des Anbaus von Kulturpflanzen mit gentechnisch erzeugter Herbizidresistenz auf das Ausmaß der Bodenerosion und der Pestizidabschwemmung"; commentary by Dr. L. Ebner (Ciba-Geigy, Basel). *Materialien zur Technikfolgenabschätzung, Heft 8* (see appendix).

[57] In Germany mulchseed is practised on no more than 1-2% of the total area of row crops. However, in sites which are particularly prone to erosion mulchseed may amount to 30-50% (personal communication Dr. Reschke, Pflanzenschutzamt Hannover).

[58] Expert report commissioned form Prof. G. Klein (Institut für Wasser-, Boden- und Lufthygiene, Bundesgesundheitsamt): "Auswirkungen der HR-Technik auf aquatische Ökosysteme"; commentary by Dr. E. Dorn (Hoechst AG, Frankfurt), in: *Materialien zur Technikfolgenabschätzung, Heft 9* (see appendix).

selection of herbicide-resistant mutants of aquatic organisms. If these organisms spread they could disturb the biocoenosis of an aquatic ecosystem, for example, by disrupting existing food chains. This could only happen, however, if the herbicides exert selection pressure on the nonresistant variants of the aquatic organism, that is, if they reduce the fitness of these variants or are toxic for them. Such effects should, in principle, be excluded by the required testing for herbicide approval. These tests may not eliminate all uncertainty with respect to the effects of herbicides on aquatic ecosystems, since testing relies on model systems and indicators. Nevertheless, herbicide leaching into surface waters is, in general, brief and concentrations are very low (in micrograms per litre). It is therefore not likely to give rise to a spread of herbicide-resistant water organisms.

14. Drift response of water organisms to herbicides is possible and can lead to (presumably temporary) changes in aquatic ecosystems. Such a response has also been observed with nonselective herbicides like glyphosate. Drift response can occur even when herbicide concentrations are several orders of magnitude below the level controlled by ecotoxicological testing. The use of nonselective herbicides could, however, also have a positive effect insofar as the number of treatments per year and, hence, the number of leaching events could be reduced.

15. It can be concluded that problems of water pollution will at least not be aggravated, and possibly even slightly improved, if there is a shift from selective to nonselective herbicides in weed control. With respect to ecotoxicology the nonselective herbicides generally come off as well or better than herbicides used up to now. Whether a reduction in the amount herbicides leached to surface waters of 10-30% represents a real improvement in ecological terms is a matter of debate.[59]

Question 4: Will the application of nonselective herbicides change phytocoenotic structures in agricultural ecosystems?

Conclusions from the discussion[60]

16. The application of nonselective herbicides in weed control can affect the phytocoenotic structure in agricultural ecosystems, that is, it can induce changes in dominance (numbers of individuals) and diversity (number of species), which extend beyond the vegetation period. The mechanisms for such changes could be reduction of seed banks in the soil and spread of weed species that remain unaffected by nonselective herbicides (incomplete spectrum).

17. Nonselective herbicides will change the spectrum of weed species in the field. They suppress weeds which may previously have been tolerated because they are poor competitors for the crop plants, and they favour weed species that reproduce later in the vegetation period. If nonselective herbicides are used in monocultures or in all crops of a rotational sequence, they are likely to cause irreversible reductions in the weed seed bank and eventually eliminate individual species from the normal weed community and, hence, the agricultural habitat. On the other hand, if a nonselective herbicide is only used once in the crop rotation sequence, then the species spectrum of the weed community ought to be sustained (perhaps at a lower population level) or it should be able to restore itself.

18. From the point of view of agricultural production a reduced weed seed bank in the soil would seem to be a positive rather than a negative factor. It would lower the weed pressure in the field and, when fewer weeds appear, then less herbicide treatment is needed—also an advantage in ecological terms. On the other hand, increased selection and spread of weed species which are not controlled by those herbicides may confront the farmer with additional agronomic problems.

19. The spectrum of weed control is not extraordinary with nonselective herbicides compared to tank mixtures or successive treatments of selective herbicides. Such treatments, routinely applied in sugar beet, for instance, also keep fields virtually free of weeds. In these cases, no additional impacts on the phytocoenosis of an agricultural ecosystem should be expected from nonselective herbicides. The same may even be true if one compares use of these herbicides with very thorough manual weeding (which was applied previously when labour costs were still extremely low).

20. Changes in the agricultural phytocoenosis, including shifts of dominance and weed spectrum biodiversity are implied in many agricultural practices, such as different tillage schemes or variations in the crops grown. Such effects are, therefore, in no way specific to the introduction of nonselective herbicides.

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[59] See section III C3 below.

[60] Expert report commissioned from Prof. E. Mahn (Institut für Geobotanik und Botanischer Garten, Martin-Luther-Universität Halle): ”Zu den Auswirkungen der Einführung herbizidresistenter Kulturpflanzen auf Ökosysteme”; commentary by Dr. M. Reschke (Pflanzenschutzamt, Hannover), in: *Materialien zur Technikfolgenabschätzung, Heft 10* (see appendix).

C IMPACTS ON AGRICULTURE

This part deals with the indirect consequences of transgenic herbicide-resistant crops. It reaches beyond the issues of biosafety and considers possible impacts on the structure and performance of modern agriculture. In Germany such impacts are, as a rule, not accounted for in regulatory frameworks for state approval of a new technology. They are nevertheless crucial for the political judgement and public acceptance of a technology and, therefore, an essential topic in a technology assessment. We considered the impact of transgenic herbicide-resistant crops on biodiversity in breeding and cultivation, on the practice and the economy of weed control, and on food supply.

1 Issues of biodiversity: Will transgenic herbicide-resistant crops accelerate genetic erosion in plant breeding and agricultural habitats?

The term ”genetic erosion” is used to designate various forms of loss of biological or genetic diversity. Its definition remains vague since reference is made to heterogeneous issues: the loss of wild species in nature, the loss of cultivars in plant breeding, the genetic uniformity of crops actually grown in the fields, lack of crop rotation and monocultures. Broadly, three problem areas should be distinguished:

- the protection of species,
- the development of plant breeding,
- good field practice in agriculture.

While these problem areas do overlap to some extent, within each of them, loss of diversity has a different meaning and implies different concepts of damage. The following table tries to summarise these differences.

In our technology assessment, all of these issues were invoked in the discussions of whether the introduction of transgenic herbicide-resistant plants might cause a loss of biodiversity; however, the arguments were varied. All the participants did agree that we are experiencing a dramatic, world-wide loss of biodiversity and genetic resources. The on-going destruction of tropical rain forests, for instance, probably eradicates thousands of species per week. While the expansion of modern agriculture has indeed added considerable negative impacts as well, it is not likely that herbicide-resistant plants will play a significant role in this respect.

DEFINITIONS OF GENETIC EROSION	CONCEPTS OF DAMAGE
Reference: Diversity of Species	
extinction of wild plant species	nature conservation; loss of genetic resources for plant breeding
elimination of weed species from agricultural habitats	nature conservation; loss of useful organisms depending on such weeds
reduction in the number of crops grown in agriculture	food supply becomes increasingly dependent on fewer crop species
reduction in the number of crops in the crop rotation sequence	increased susceptibility to pests and phytopathogens, increased use of pesticides, environmental damage
Reference: Diversity of Plant Varieties	
extinction of local cultivars (land races) at centres of genetic diversity	loss of genetic resources for plant breeding
fewer crop varieties cultivated in fields	increased susceptibility to pests and phytopathogens; monopolising the seed market
reduction in the number of registered (marketed) crop varieties	same as above plus loss of options for farmers
elimination of cultivars from breeding programmes	loss of genetic resources for plant breeding

Arguments were raised that genetic engineering might reduce the level of variability within cultivars, thereby destroying genetic resources for plant breeding. Other arguments addressed possible losses of diversity in the system of crop husbandry at large. Key questions were whether, with the introduction of herbicide-resistant plants, the spectrum of crop species actually grown in the fields would become narrower and the number of cultivars for each crop smaller. It was further assumed that herbicide-resistant crop varieties monopolise the seed market, either because of economic advantages or privileges resulting from patent law. The main objection to such scenarios was that lack of diversity within the spectrum of crops and varieties cultivated was the result of the political, legal and, above all, economic conditions of modern agriculture, and not the result of any particular breeding technique. A good test would be to ask whether the problems would, in fact, be avoided if the technique were changed, i.e. if conventional breeding techniques were used instead of genetic engineering.[61]

Question 1: Will transgenic herbicide-resistant crops cause further losses of biodiversity and genetic resources?

Conclusions from the discussion

1. The main reason for global loss of plant biodiversity is continued extinction of wild species in natural ecosystems. This implies a dramatic loss of genetic resources for plant breeding. The introduction of transgenic herbicide-resistant crops will not have a significant impact on this process. Some key factors are the political and economic pressures to harness ever more land for agricultural and industrial use, high population growth, rapid climate change, ill-conceived nature conservation policies, and the displacement of local, traditional cultivars (land races) still used in the Third World by newly developed, high-yield varieties.

2. Extensive use of nonselective herbicides in conjunction with transgenic herbicide-resistant crops could lead to the elimination of rare weed species from the local seed banks and, hence, from the local agricultural habitats. Although the effect would be local, it would nevertheless constitute a loss of biodiversity in terms of nature conservation which requires that the existing spectrum of species in all habitats be preserved. In terms of genetic resources, however, even the elimination, for instance, of a rare weed species from an entire region would not imply any permanent loss. For breeding purposes, it is sufficient if a species continues to exist in any other site or nature reserve. Genetic resources are lost, however, when ecotypes of a species, i.e. regionally adapted variants, become extinct.

3. Genetic resources for plant breeding are lost on a massive scale because, in the Third World, local, traditional cultivars (land races) of important crops grown in the centres of genetic diversity are now increasingly displaced by modern, high-yield varieties. Although the ”globalisation” of agriculture, prevalent in the industrialised countries, is a driving force behind this process, herbicide-resistant plants are not a significant factor in this respect.

4. Maintaining the level of biodiversity in plant breeding does not seem to be a problem in Central Europe at present. In contrast to nature conservation, the protection of genetic resources can be adequately ensured by gene banking and cultivation at breeding stations. Moreover, the continuity of genes from older cultivars is guaranteed through their inclusion in the gene pools of new varieties from which old traits can be retrieved through suitable crossing. It is true that, in this case, older cultivars will no longer be grown and developed in the fields; nevertheless, this is an unavoidable price to pay, since breeding is by definition designed to replace old varieties with new ones in the field.

5. The fact that transgenic varieties are derived from a few transformed cells identically replicated (cloned) in cell cultures does not imply a loss of biodiversity. The development of transgenic varieties has no influence on the amount of genetic variability within the cultivar. The cloned cells still contain all the genetic variability which is, in turn, expressed when these cells are crossed with others in the process of developing a new variety. The genetic variability between varieties is, in contrast, quite limited (see below). However, this indicates, a lack of diversity in agriculture and not a loss of genetic resources.

Question 2: Will transgenic herbicide-resistant crops reduce the diversity of crops and varieties grown in agriculture?

Conclusions from the discussion

6. Diversity in crop varieties has increased rather than decreased over the last decade, both in terms of number of varieties registered by plant breeders and number of varieties actually grown in the fields. There is, nevertheless, reason to infer genetic erosion since, for each crop species, few varieties dominate in cultivation and all varieties are closely related. Cultivars that are closely related genetically (i.e. homogeneous) imply higher risk of yield loss through pressure from pests and phytopatho-

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[61] Expert report from Dr. H. Umbach, Dr. J. Zeddies and Dr. R. von Broock (Kleinwanzlebener Saatzucht AG (KWS) Einbeck): ”Auswirkungen der Herbizidresistenz-Technik auf die Züchtungspraxis und die genetischen Ressourcen”; commentary by C. Freudling (Saatgut-Aktions-Netzwerk, Fürth), in: *Materialien zur Technikfolgenabschätzung*, *Heft 11* (see appendix).

gens. This certainly applies if the plants are protected only by the mechanisms of vertical pest resistance which can be easily overcome by mutation in the pest organisms.

7. The low number of varieties actually cultivated in the fields results from economic and agronomic considerations which bear no relation to herbicide-resistant plants or genetic engineering in general. The best available varieties are usually also the most successful on the market. And, farmers prefer homogeneous stocks of plants because these are easier to cultivate and harvested crops easier to process.

8. The current law of plant variety protection (*Saatgutverkehrsgesetz* in Germany) reinforces the trend towards homogeneity, because it requires a test of "uniformity" before a variety can be registered and marketed. The aim of this test is to ensure the quality of the seed a farmer purchases, and to guarantee that all plants of a variety are suitable for a designed purpose, for instance, wheat for baking bread or potatoes for making chips. In addition, registration procedures require that new plant varieties meet the legal test of "value for cultivation". This makes the market for seed products highly transparent, so that farmers can easily and shift en masse to the varieties they find most suitable for their area. Finally, the legal privilege of free use of available plant varieties for breeding, initially designed to preclude commercial monopolies and promote diversity on the seed market, paradoxically encourages technical uniformity of seed products: Since all breeders use the best available varieties for further development, they all end up with very similar products.

16. Economic calculation and political regulation (quotas) determine which crop species farmers choose to cultivate on their land. The particular crop rotation sequence is decided within the constraints of agronomic needs—usually long before a specific variety of crop is chosen and irrespective of whether special traits such as herbicide resistance are available in the cultivars. Herbicide-resistant varieties could attract farmers, however, if they offer clear technical and economic advantages. This is probably the case for sugar beet, at present. But any further expansion of the area of sugar beet cultivation would be prevented by quota restrictions in Europe. In general, the availability of herbicide-resistant varieties is not likely to determine farmers' decisions about crop species to be grown; it will therefore have no significant impact on the level of diversity in crop husbandry.

2 Agronomic effects of transgenic herbicide-resistant crops: technical gains, resistant weeds, and integrated crop protection

The application of nonselective herbicides with transgenic crops is still at the beginning stage in Germany. Although the number of field trials carried out under practical conditions is growing fast, few herbicide-resistant crops have been placed on the market.[62] Therefore, judgements about the agronomic advantages nonselective herbicides may have for the farmer are provisional and subject to further demonstration in practice.

In our technology assessment various advantages were claimed[63]:

- Weed control would become easier and more flexible. The underlying assumption was that, with nonselective, broad spectrum herbicides. the application of tank mixtures herbicides could be spared, that problem weeds would be effectively controlled and that the opportunities for postemergence treatment would increase.
- The farmer can use a wider range of herbicides and avoid one-sided (nonrotational) applications. This is the minimum advantage claimed for nonselective herbicides, since it would be valid even if these herbicides were otherwise not superior to the selective ones used up to now.
- With postemergence, nonselective herbicides, economic threshold criteria can be applied, i.e. herbicide treatment can be spared if the anticipated costs of yield loss from weeds are less than the costs of the herbicide needed to control those weeds.
- The farmer has more options to shift to new systems of crop husbandry, such as direct drilling, conservation tillage mulch cropping and mixed cropping, because these systems will be easier to manage when postemergence, nonselective herbicides can be applied.
- Farmers gain flexibility with respect to which crop species he can grow in the rotational sequence, since the nonselective herbicides have

[62] According to reports from AgrEvo, over 1700 field trials have been carried out with oilseed rape, maize, soybean and sugar beet resistant to glufosinate (autumn 1996). Resistant oilseed rape was approved in Canada in 1995. Approval of glufosinate resistant maize is expected to be granted in the U.S. in 1997, soybean and sugar beet in 1998; see Rasche *et al*. (1996). Monsanto achieved U.S. approval of its glyphosate resistant soybeans in 1994. These soybeans have been cultivated on 1-2% of the soybean area in the U.S. in 1996 (Monsanto, press release Information Sojabohne).

[63] See also Wilcut *et al*. (1995); Burnside (1996: 400).

low persistence and no carry-over effects to the next vegetation period.[64]

Most of these claims were controversial. It was argued that the advantages, although possible in theory, could not be achieved in actual practice, and that they were outweighed by disadvantages.

In particular, doubts were raised whether the nonselective herbicides currently under discussion would not also have incomplete spectra and, therefore, not be clearly superior to the selective herbicides already in use. On the other hand it was argued that selective herbicides could be driven off the market, leaving the farmers with fewer rather than more choices of herbicides for weed control. In general, it was conceded that nonselective herbicides increase the technical options to shift to new systems of crop husbandry. However, the practical relevance of such options was denied, since under existing economic conditions there would be little scope for implementing these systems.

Arguments over possible agronomic disadvantages focused mainly on the emergence of herbicide-resistant weeds. Are nonselective herbicides particularly likely to produce resistant weed populations when they are extensively applied? Were this the case, then these herbicides would become useless for agriculture. Resistant weeds can evolve through gene flux from the crop plant (hybridisation); however, the most relevant mechanism would be spontaneous mutations in individual weeds and selection of the mutants through herbicide application.

A long debate in the technology assessment addressed the question of whether or not the use of nonselective herbicides would be compatible with the standards of integrated crop protection. These standards require that the farmers minimise pesticide use and try instead to suppress weeds indirectly through preventive cultivation measures and good agronomic management, for instance, growing competitive crop varieties, increasing the number of crops in the rotational sequence, or using ground cover or mulch crops to suppress weed growth. Direct measures, including treatment with herbicides, should be adopted only when weed problems are so severe that the cost they might incur (in terms of yield loss) would surmount the economic threshold of the cost for additional weed control; residual weed populations below this level are viewed not merely as tolerable, but also as desirable.

There was agreement that the current use of herbicides does not meet the standards of integrated crop protection. The idea that priority must be placed on preventive measures, implying a revision of current crop rotation sequences and cultivation systems, breaks down in the face of economic constraints. Nonselective herbicides are should not change this situation profoundly. The question is, rather, whether they would improve it slightly or make it even worse. Two issues were discussed in this respect: Are economic thresholds more likely to be observed if nonselective herbicides are applied? Can the agronomic functions of residual weeds in cultivated fields be maintained?[65]

Question 1: Do nonselective herbicides provide more flexibility and new options in weed control and crop management?

Conclusions from the discussion

1. Nonselective herbicides applied in conjunction with transgenic herbicide-resistant crops provide additional options for postemergent weed control. They extend the range of choice for herbicide rotation.

2. Actually, nonselective herbicides could reduce the total number of herbicides applied in agriculture. If they have significant advantages over the herbicides currently used, they could replace these in many areas. This could occur even if nonselective herbicides were applied only once in the crop rotation sequence, for instance, when resistance to one and the same nonselective herbicide were engineered into the common cultivars of all row crops.

3. While new and better products can always drive older ones off a market, there is no reason to suppose that this will be the case for nonselective herbicides. Selective herbicides are widely used with many crops at present and they will keep a share of the market; it is unlikely that they would completely disappear as options for herbicide treatment.

4. Postemergence, nonselective herbicides can

[64] On the discussion of possible cost benefits for farmers see section II C3 below.

[65] Export report on organic impacts commissioned from Prof. K. Hurle (Institut für Phytomedizin, Universität Hohenheim): "Mögliche Veränderungen in der landwirtschaftlichen Praxis durch die HR-Praxis"; commentary by Dr. P. Niemann (Biologische Bundesanstalt für Land- und Forstwirtschaft, Braunschweig), in: *Materialien zur Technikfolgenabschätzung, Heft 12* (see appendix). Expert report on integrated crop production commissioned from Prof. R. Heitefuß, Dr. B. Gerowitt and Dr. H. Steinmann (Institut für Pflanzenpathologie und Pflanzenschutz, Universität Göttingen): "HR-Technik und integrierter Pflanzenschutz"; commentary by A. Gnekow-Metz, in: *Materialien zur Technikfolgenabschätzung, Heft 13* (see appendix).

improve weed control. They allow more thorough elimination of problem weeds and reduce the risks of yield loss through herbicide application, since the crop plants are insensitive. Significant advantages might be expected particularly for those row crops with wide row distance such as sugar beet or potatoes, but also for oilseed rape and maize. All of these crops are subject to high weed pressure.[66]

5. These advantages may not materialise, however, if nonselective herbicides also have incomplete spectra and must therefore be applied in combination (tank mixtures) with other herbicides or in a series of repeated treatments. Although glyphosate and glufosinate have a broader spectrum than most other herbicides, their spectrum is by no means complete.[67]

6. With transgenic herbicide-resistant crops, the farmer gains flexibility with respect to the time span available for postemergence treatment. If necessary, i.e. when unexpected weed problems arise, a treatment that was spared previously can be recovered later without harming the crops. This assumes that nonselective herbicides indeed need not be applied in herbicide combinations and that they do less damage to crops than the selective, postemergence herbicides currently available.

7. Theoretically, transgenic herbicide-resistant crops extend the range of technical options for systems of crop husbandry, such as direct drilling, mulchseed or intercropping, which imply more effective soil conservation. Practically, however, transgenic herbicide-resistant crops will do little to enhance a shift to such systems. Ground cover to prevent weed growth in row crops, for instance, was possible before herbicide-resistant crops were available; but, for economic reasons, it has been little used. Techniques of minimal tillage (direct drilling) are more often cost-effective and could be boosted somewhat by the introduction of herbicide-resistant crops, but large-scale intercropping will hardly be economically viable within the framework of conventional agriculture.

8. With transgenic herbicide-resistant maize, a monoculture could possibly be better managed. But monocultures are never advisable anyway, according to the principles of good field practice.

9. The use of glyphosate and glufosinate can allow greater flexibility in crop rotation in certain cases, because they have low persistence and are unlikely to have carry-over effects to the next vegetation period. However, the choice of crops to be grown is above all contingent upon economic factors, and the applicability of nonselective herbicides will hardly be a decisive factor for this choice.

Question 2: Are nonselective herbicides particularly prone to produce herbicide-resistant weed populations?

Conclusions from the discussion

10. There is a certain risk with any herbicide of becoming ineffective with time because of the spread of resistant weeds. The problem is not specific to herbicides which are applied in conjunction with transgenic herbicide-resistant crops. Resistant weeds presuppose that resistant mutants evolve which are fit enough to survive and reproduce. The rate of spread will then depend on the selection pressure exerted on the weed population. Selection pressure, in turn, will depend on the characteristics and management of the herbicide, e.g. its spectrum, phytotoxicity, the rate and frequency of its application, or herbicide mixtures.

11. Since nonselective herbicides with a broad

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[66] Reschke (1996) summarises findings from field trials with transgenic herbicide-resistant sugar beets:

> ”Two applications of three litres of BASTA per hectare (one at the four-leaf stage, the other at the eight-leaf stage of the sugar beet) provide good control of nearly all weeds. If weather conditions are favourable and plant growth enhanced, two applications of 1.5 litres per hectare (plus an additive of oil) provide sufficient coverage, even for fool’s parsley (*Aethusa cynapium*) which is otherwise difficult to control. Annual nettles (*Urtica urens*) which occur in rare instances are somewhat less sensitive if weather conditions are not favourable; the same applies (although to a lesser degree) to cleavers *(Galium aparine)* and field pansy (*Viola arvensis*). These require higher dosage, as a rule, or a supplement of one litre of GOLTIX per hectare. This supplement also prolongs the herbicidal effect and, in combination with 1.5 to 2 litres of BASTA is optimal in terms of effectivness and cost of weed control.”

Crop tolerance to glufosinate has been ranked very high (9.45 of 10 points) by farmers who cultivated transgenic herbicide-resistant oilseed rape in Canada, according to a survey by AgrEvo (Rasche *et al*., 1996: 10). Reschke (1996) reports comparable results with the application of glufosinate in transgenic herbicide-resistant sugar beet. With glyphosate-resistant sugar beet sufficient control can be achieved with two applications of three litres of the herbicide (Reschke, personal communication).

[67] In herbicide-resistant sugar beet appreciable reductions in the rate of herbicide application can be achieved even if glufosinate is used in a tank mixture with Goltex: a total of five to six litres per hectare (in two applications) versus eight to nine litres per hectare (in three to four applications); see Reschke 1996. Reductions with glyphosate in sugar beet will be comparable. In soybean glyphosate can replace a combination of five different herbicides and reduce the amount of herbicides by 30%—from 1.13 to 0.74 kilogram per hectare (Monsanto, press release Information Sojabohne, December 1996).

spectrum and high phytotoxicity exert a greater pressure on weed populations than conventional herbicides, they will, in principle, increase the risk that resistant weeds would be selected, provided that suitable mutants exist.

12. The probability of resistant mutants evolving with sufficient fitness depends on the target enzyme of the herbicide. In the case of sulfonylurea, resistance can evolve easily because single mutations in the target enzymes of weeds suffice to render the herbicide ineffective. On the other hand, this risk seems to be relatively small in the cases of glyphosate and glufosinate. These herbicides have a long history of extended use (not involving transgenic plants), yet no resistant weed mutants have been observed. Nevertheless such mutants may still be possible.[68] The risk of spontaneous mutations conferring resistance to weeds may be further reduced if the mechanism of herbicide resistance in crop plants is derived from bacterial genes.

13. No reasons were given in the technology assessment to support the hypothesis that nonselective herbicides would be routinely misused and that they are therefore more likely to lead to the selection of resistant weeds. Rising costs provide an incentive to reduce the rate of herbicide application and avoid excessive treatment. Crop sequences may not always correspond to the rules of good field practice, but this is because of economic considerations and not the options for weed control.

14. The use of nonselective herbicides with monocultures or without herbicide rotation through all stages of a crop sequence is not advisable, since it clearly increases the risk of herbicide-resistant weeds. Furthermore, volunteer plants from the previous vegetation period will be difficult to control if all crops in a rotation sequence are resistant to the same herbicide. These disadvantages could probably be avoided if nonselective herbicides were used only once in a rotational sequence.[69]

Question 3: Is the application of nonselective herbicides in transgenic herbicide-resistant crops compatible with the standards of integrated crop protection?

Conclusions from the discussion

15. Nonselective herbicides improve and extend the options for herbicide treatment. As a result, they will probably stabilise herbicide treatment as a strategy of weed control. The current use of herbicides does not comply with the standards of integrated crop protection. Existing options for indirect control through preventive management (in particular, through appropriate cultivation measures) are neglected because herbicides provide a more attractive alternative. Preventive weed management not only implies increased labour input and investment costs for new machinery, but also technical difficulties, such as increased dependency on the weather, unpredictable effectiveness, or management problems with ground cover etc. To the extent that these constraints would also apply for nonselective herbicides, their possible contribution to integrated crop protection will be modest at best.[70]

16. In theory, postemergence, nonselective herbicides are more in line with the ideas of integrated crop management because they improve the prospects for cultivation with direct drilling and mulch cropping, as well as the feasibility of economic thresholds to be observed in herbicide use. In practice, however, nonselective herbicides will probably have little effect in this respect. Economic thresholds are not widely recognised by farmers in weed control, and the availability of nonselective herbicides will probably not make a great difference.[71]

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[68] Rasche *et al*. (1996: 9) emphasise that any mutation in the target enzyme of glufosinate (the glutamin synthetase) would be lethal for the plant, and hence the spontaneous development of herbicide resistance in weeds is unlikely. Consequently resistant weeds have never been observed, despite wide ranging application of glufosinate over a period of more than 10 years. On the other hand, glyphosate resistance has apparently been detected recently in *Lolium rigidum*. This weed has accumulated several resistance mechanisms; an Australian biotype shows multiple resistance to at least nine dissimilar herbicide chemistries, according to Preston *et al*. (1996).

[69] See also the summary of Thill (1996: 336):

> ”The risk of selecting herbicide-resistant weeds in a [herbicide-resistant crop] is no greater than using a selective herbicide in a naturally tolerant crop. In either case repeated use of the same herbicide or herbicides with the same mode of action will eventually select for herbicide-resistant weed biotypes. This can be prevented or greatly delayed by using effective integrated weed management strategies in all parts of the crop producvtion system. Most importantly, avoid using the same herbicide or herbicides with the same site of action routinely in any cropping system.”

[70] As one participant in the technology remarked, the introduction of conservation tillage (minimal tillage) has been thwarted by the fact that, without the use of the plough, new seed-drilling techniques are required to cope with the mulch and surface weeds. ”This means the farmer has to buy a second drilling machine.”

[71] This tentative conclusion was criticised by one participant, who claimed that herbicide-resistant crops are a real step towards integrated crop protection,

> ”because for the first time a herbicide will be available which is effective against all weeds, including the large ones. The biggest barrier to observing economic

17. Even if economic thresholds are not observed, farmers have better opportunities with postemergence, nonselective herbicides to reduce the rate of herbicide application, depending on actual weed infestation in the field. This could lead to appreciable reduction in the amount of herbicides applied.[72]

18. Herbicide treatments which leave fields completely void of any residual weeds ("clean weeding"), contradict the standards of integrated crop protection. It is doubtful, however, whether nonselective herbicides would have such an effect. Glyphosate and glufosinate, for example, although they have a broad spectrum and are more effective than previously available selective herbicides, are far from leaving fields permanently free of weeds. As systemic (glyphosate) or contact (glufosinate) herbicides, they act on plants which appear in the field, i.e. they only control those weeds which have already emerged. Weeds can grow up again immediately after herbicide application, from the seeds in the soil. In crops which had previously been treated with combinations of herbicides, nonselective herbicides will not mean increased suppression of weeds.[73]

19. Weed stocks which re-emerge after application of nonselective herbicides may not be sufficient to fulfil the agronomic functions ascribed to residual weeds as a factor in integrated crop protection, namely, diverting pests from crops or harbouring beneficial organisms. What would certainly not be compatible with the principles of integrated crop protection would be if, due to the loss of residual weeds, more insecticides had to be applied to fields already treated with nonselective herbicides. As yet, there are no signs that this is in fact the case. Moreover, the so-called positive agronomic functions of residual weeds are largely a matter of theory; whether they occur in practice, has yet to be demonstrated. Residual weeds, on the other hand, can also serve as habitats for plant pests and they increase the risk of transmission of plant disease.

3 Economic effects of transgenic herbicide-resistant crop plants: profits, costs, and concentrations

Discussions about the economy of transgenic herbicide-resistant plants used the current system of intensive agriculture as the frame of reference, and considered possible impacts of those plants on the economic situations of individual farmers and the structure of seed production and markets.[74]

Measuring costs and benefits in terms of prices of agricultural inputs and products is a standard approach in economics. But it disregards "external" costs, in the case of herbicides, possible damage to the environment, or the costs of developing and testing herbicides. This may be methodologically justifiable, if conventional agriculture is chosen as the frame of reference. Since the evidence presented in our technology assessment suggests that the ecological and social consequences of nonselective herbicides will not differ significantly from the consequences associated with current herbicide use, external costs should be comparable and may, therefore, be disregarded.

Comparison to the status quo in conventional agriculture and current practices of herbicide use was not accepted by all participants as a valid approach, however. The dispute over this point notwithstanding, there was agreement that it would indeed be reasonable and legitimate to include the external costs of herbicide applications in conventional agriculture as part of a comprehensive economic assessment of herbicide-resistant crops. To that extent it was at least implicitly conceded that market prices for farmers and consumers are not the sole criteria for economic costs and benefits.

Nevertheless, calculations of external costs raise unresolved methodological problems. There is no way to monetarise ecological, social and political consequences without making arbitrary

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thresholds in weed control has been the fear of not being able to deal with large weeds with certainty."

[72] The standards of integrated crop protection are not clearly defined. It would be inappropriate to reject current practices solely because they do not comply with the concept of economic thresholds. As a participant writes,

> "Instead of adopting the economic thresholds proposed by the scientists, farmers have frequently reduced the amounts of herbicide they apply by up to a half if weed cover is low, with the same result, namely that a residual weed population remains which does no economic damage."

[73] As one participant notes: "In view of the lower persistence of nonselective herbicides, residual weeds are more likely to be in the fields than previously."

This argument fails, however, if glufosinate is applied in a tank mixture with a herbicide which is explicitly added in order to prolong herbicidal effects.

[74] Expert report commissioned from Prof. V. Beusmann (FSP Biotechnik, Gesellschaft und Umwelt, Universität Hamburg): "Betriebs- und volkswirtschaftliche Auswirkungen des Einsatzes herbizidresistenter Nutzpflanzen (HR-Technik)"; commentary by Prof. R. Müller (Institut für Agrarökonomie, Universität Kiel), in: *Materialien zur Technikfolgenabschätzung, Heft 14* (see appendix).

assumptions. The technology assessment did not, therefore, try to provide such calculations, and the results remain a matter of speculation. It was clear, however, that there was no agreement among the participants about whether or not a comprehensive balance of all costs and benefits would show, in the final analysis, that the use of herbicides in modern agriculture was not economical.

Calculating the economic gains individual farmers might harvest from using nonselective herbicides involves a high degree of uncertainty, at present. Since transgenic herbicide-resistant crops have hardly arrived on the market, seed prices have not yet been established. Nor are the prices for nonselective herbicides constant. The report delivered in the technology assessment based its calculations on 1992 market prices. In addition, it made assumptions about reductions in the rate of herbicide application and further advantages from nonselective herbicides that are, in part, controversial.

With respect to possible impacts from transgenic herbicide-resistant crops on the seed business, the main point made was whether concentrations among breeding companies, and between breeders and herbicide manufacturers become more likely, and whether herbicide-resistant crop varieties could be pushed to gain a monopoly on the seed market. In this context, the discussions also considered the argument frequently advanced in public debates that farmers would become economically more dependent because they would be forced to buy herbicide-resistant seeds together with the matching nonselective herbicide in a ”package”.

Question 1: Are transgenic herbicide-resistant crops and nonselective herbicides more cost-effective for the farmer?

Conclusions from the discussion

1. The use of nonselective herbicides in conjunction with resistant crop cultures benefits farmers economically insofar as it reduces the total amount of herbicides used at present and, through postemergence treatment, minimises yield loss from crop damage. Calculations suggest that there is a clear cost advantage for sugar beet, perhaps a saving of up to 50%. Smaller advantages can be expected for maize and soybean, followed by winter rape and potato. If fields are heavily infested with problem weeds, some benefits may be derived for all crops.

2. The calculated savings will become less or disappear altogether if nonselective herbicides, too, have incomplete spectra and, therefore, have to be applied in combination (tank mixtures) with other herbicides or in repeated treatments in order to be fully effective. For glyphosate and glufosinate, however, gaps in the spectrum will not totally rule out all the calculated benefits.[75]

3. Given the competition on agricultural markets, it is to be expected that financial benefits for the farmers would have to be passed on to the consumers in the form of lower product prices sooner or later.

4. In many cases nonselective herbicides will probably not offer tangible price advantages compared with those herbicides used at present. Nonselective herbicides will only add to the number of postemergence herbicides from which farmers can choose, and they must face competition from products already established on the market. Under such conditions, nonselective herbicides may have a competitive edge, if it turns out that they do indeed mean easier management and greater flexibility of weed control for the same price.

Question 2: Will transgenic herbicide-resistant cultivars gain a monopoly on the seed market and make farmers more dependent on herbicide manufacturers?

Conclusions from the discussion

5. No single crop variety will come to dominate the seed market just because it has been complemented with transgenic herbicide resistance. If herbicide resistance constitutes a real economic advantage, then it is rather to be expected

[75] According to calculations by Reschke (1996), maximum costs for weed control in sugar beet would be DM 250 per hectare (two applications each of three litres of Basta (glufosinate) plus one kilogram of Goltix); this implies a savings of DM 100 (30%) compared to the cost for current applications of selective herbicides (DM 350). Savings increase up to 45% if fields are infested with fool’s parsley or if mulchseed has been applied (DM 450).

The figures may be even more favourable with glyphosate-resistant sugar beet: about DM 100 for two applications with two to three litres each (Reschke, personal communication). According to IHE (1994: 42/44) data from the notifier suggest that savings could amount to 50-70% (75 ECU per hectare instead of 150-250 ECU); if problems with nettles are taken into account the savings might still be 30%. On the other hand, Meisser and Guenat (1996: 27) estimate a gain of no more than 2-7% on gross margin for sugar beet in Swiss agriculture. With respect to glyphosate-resistant soybeans herbicide costs are reduced from $54.42 per hectare (1993/94) to $23.30 U.S. (1996). Although the seeds are 25% more expensive famers still gain from the reduction in the amounts of herbicides used (Monsanto, press release Information Sojabohne, December 1996).

that it would be engineered into all the major cultivars which have a significant market share at present. This will also apply to the cultivars of sugar beet currently grown.

6. Economic concentration is likely to continue in the seed business, as indicated by trends in the US and many European countries. The chronic economic crisis in agriculture is the main driving factor behind this trend. To a certain extent, modern biotechnology could accelerate this process, if it renders competitive breeding more capital intensive. Whether the number of varieties marketed would decline as concentration increased is an open question. Economic theory does not warrant a prediction of that kind.

7. The assumption that chemical companies which become involved in the seed business would try to force farmers to buy ”packages” of herbicide-resistant cultivars and matching nonselective herbicides is not realistic. In economic terms, it would be definitely more profitable to sell the seed and the herbicide separately. A crop variety which can only be purchased together with a herbicide is by definition at a disadvantage compared to a variety which is available without an additional product inseparably linked to it. The same applies in reverse for the herbicide, if it could only be sold together with some specific crop variety. For the herbicide manufacturer, the ”package” would, in any case, only be conceivable if the herbicide had no application other than that associated with the company’s own herbicide-resistant crop varieties, and this is obviously an absurd assumption for all herbicides.

8. Seed companies, on the other hand, could indeed expect extra profit if they were able to monopolise herbicide resistance genes for their own crop varieties. This is true, however, irrespective of whether a company offers a ”package” including the nonselective herbicide or whether the herbicide is freely available on the market.

9. For herbicide manufacturers, in contrast, it would be sheer economic nonsense to restrict sales of nonselective herbicides to exclusive packages with a limited number of transgenic varieties. They are bound to exploit to the full the limited period of patent protection for their herbicides. Therefore, if herbicide manufacturers own resistance genes, they must have an interest in having them transferred to as many varieties as possible, whether they own these varieties or not. From their perspective, it might even be economical to provide the herbicide resistance genes freely, i.e. without license fees for breeders. There are some indications that this is, in fact, what is being done.[76]

4 Food supply: Is a contribution to be expected from transgenic herbicide-resistant crops?

It is not particularly sensible to ask whether transgenic herbicide resistance is an innovation which can contribute significantly to solving the problems of world food supply. This is obviously not the case. In our technology assessment, the question was therefore broadened to include the possible contribution of herbicides in general as a strategy for weed control. Discussions focused on agriculture in Third World countries.[77]

Participants had no doubts that world food supply is clearly both a social and political question of distributive justice, and a technical question of increased production in agriculture. They thus by-passed much of the ill-conceived polemics in the public debate, which tended to play the need for political reform off against the need for technological innovation and vice versa.

Whereas all the participants agreed that food production in the countries of the Third World must be increased, the strategy to be chosen remained a matter of controversy. Some placed their hopes on the development of smallholder farming and the improvement of indigenous, ”appropriate” agricultural technology. Proponents of this scheme excluded any use of herbicides. Others, in contrast, argued that a subsistence economy of smallholder farmers would not feed urban masses and that therefore industrialised, high-input agriculture is indispensable in the Third World as well. From their perspective, herbicides and also herbicide-resistant crops were a possible technical option. There was further disagreement about whether herbicides could be considered a useful option at all for weed control under the natural, social and economic conditions of agriculture in Third World countries (tropical climates, large sectors of subsistence economy, and cheap labour).

[76] It seems difficult to anticipate commercial strategies of herbicide manufacturers. These must, of course, try to get a return on investment from licencing the herbicide resistance gene, if the herbicide is off patent, which is already the case for glyphosate and will be the case for glufosinate in a few years.

[77] Expert report commissioned from S. Neubert and J. Knirsch (Pestizid-Aktions-Netzwerk, Hamburg): ”Der Beitrag des Anbaus herbizidresistenter Kulturpflanzen für die Ernährungssicherung in der Dritten Welt”; commentary by Prof. K. Leisinger (Ciba Geigy AG, Basel), in: *Materialien zur Technikfolgenabschätzung, Heft 16* (see appendix).

It was not possible to deal with these issues adequately in our technology assessment . The following conclusions are preliminary remarks to an ongoing discussion. The controversy over policies for agricultural development in the Third World reflects the general battle over whether industrialised farming with chemical inputs or organic farming with appropriate technology should constitute the model for the future of agriculture. It became clear in the technology assessment, however, that both sides face a battery of unresolved problems. For instance, it has yet to be demonstrated how extended industrialised, high-input agriculture can be ecologically stabilised in tropical climates and whether it would constitute a sustainable basis for increasing food production. On the other hand, it is not clear how the productivity of farming systems which rely on ”appropriate” technology and reject any chemical inputs can be increased to such a degree that food supply would be guaranteed in the future.

Question 1: What type of agriculture is required in Third World countries to guarantee food supply for a growing number of people? Should smallholder farming and industrialised agriculture be played off against one another?

Conclusions from the discussion

1. Hunger is endemic in many countries of the Third World, not because there is a lack of food, but because there is a lack of income. Domestic production of food has increased considerably in recent years because of the ”green revolution” among other factors. Food supply is nevertheless not guaranteed since poor people, especially those in underdeveloped rural areas, cannot afford to buy food.

2. At present, hunger is more a problem of inadequate distribution than of inadequate production. To solve this problem, political reform and economic development are needed, and not just new technology; and transgenic herbicide resistance engineered into crop plants is certainly not part of the solution. On the other hand, given continued growth of the world population, food supply will again become a problem of absolute, available quantities of food products. Therefore, technological innovations which increase agricultural productivity will continue to be crucial for future food supply.

3. Problems of hunger are most severe for people living in rural areas. To feed these people, smallholder farming is an important basis and should be further developed. On the other hand, it cannot be expected that smallholder farming would produce sufficient food surpluses to feed the masses of people in the expanding urban agglomerates of the Third World.

4. A dramatic increase in Third World agricultural productivity is indispensable. One possible solution might be a ”dual system” of agriculture which relies, on the one hand, on a sector of smallholder farming producing mainly for self-subsistence in rural areas and, on the other hand, on a high-input, industrialised farming sector producing for urban populations. However, a ”dual system” of this nature would only be able to avoid breakdowns in food production and supply in the long run, if industrialised agriculture can be made ecologically sustainable, particularly in tropical climates.

5. Furthermore, a ”dual system” policy would seem to tolerate Third World agriculture’s disintegration into separate sectors, a traditional one and a modern one. The effect might well be that the rural areas become even more marginalised. In fact, it might be preferable to modernise agriculture and develop the infrastructure throughout all rural sectors and areas. Under this option smallholder, labour-intensive farming would be guaranteed a significant place in agricultural production and it would have to be promoted. In general, the development of rural areas will be the key factor for comprehensive economic progress in many countries of the Third World.

6. It must be emphasised that increased agricultural production is a necessary but not sufficient condition to guarantee food supply. Problems of just distribution must be solved by political means. This includes no discrimination and a ”fair share” for Third World countries within the international trade system.

Question 2: Can herbicides and hence nonselective herbicides in combination with transgenic herbicide-resistant crops be applied usefully in Third World agriculture?

Conclusions from the discussion

7. Whether or not herbicides are a useful option for weed control in Third World countries will depend on regional and sectoral factors, farm size, cultivation systems and crops. Herbicides will not, as a rule, be used by smallholder farmers because they lack cash income to buy commercial inputs, such as chemicals or transgenic seeds. And, since unemployment is high in rural areas of the Third World, manual weed control would appear to be a suitable alternative. Therefore, if subsidies for chemical inputs are available, they should be invested in pest control

(insecticides or fungicides) rather than in weed control (herbicides). Manual weed control is rational in economic terms, despite the fact that it may be otherwise undesirable to use much of the labour force in rural areas, especially women and children, to do the hard work of hoeing.

8. On the other hand, herbicide use can be an option for middle to large-sized, intensive farms whose production is based on chemical inputs and machinery. Whether or not herbicide use would be profitable, and would in fact increase yields and income, must assessed case by case. This assessment will rest with the individual farmer in the final analysis.

9. Technical specifications for herbicide application (dosage, effectiveness) are different for tropical climates than for more moderate climate zones. Some of the most urgent weed problems in tropical zones, such as parasitic weeds, can hardly be controlled by herbicides, since damage to crop roots will have already occurred before the weeds appear in the fields. For many crops which are highly infested by parasitic weeds, like sorghum or millet, herbicide use is also out of question for another reason: since these crops are typically grown by smallholder farmers who cannot afford chemical inputs. On the other hand, a number of important crops to which herbicides are applicable, in principle, are also less susceptible to parasitic weeds. Therefore, a general argument that herbicides, including nonselective herbicides, cannot be used effectively for weed control in tropical climates is not warranted.[78]

10. Yield increases which result from high chemical and modern machinery inputs can only be sustained in the long run, however, if the severe ecological problems in tropical agriculture can be resolved—problems of soil fertility and soil erosion above all. It is mainly in terms of large-scale monocultures that herbicide application will be technically and economically viable. But exactly these cultures are the ones which cause the most severe problems of soil erosion. Our technology assessment considered the question whether or not transgenic herbicide-resistant crops and nonselective herbicides could be used to improve this situation, for instance, by making mixed cropping in large, monocultural fields a feasible technical option. Opinions were divided over this point. In any case, there are no indications that such a strategy would be adopted in practice. Nonselective herbicides do, however, improve the prospects for shifting to soil protecting methods of conservation tillage (minimal tillage).

[78] Gressel (1996) provides a much more optimistic assessment of the possible role of herbicide-resistant crops in Third World countries. He reports efficient control of parasitic weeds, such as broomrape (*orobanche*) and witchweed (*Striga*), as well as *Cyperus* through glyphosate, because the herbicide is translocated. ”At present the only cost-effective control for *Cyperus* and *Striga* is the too-commonly practiced abandonment of farms.” (243)

PART III: NORMATIVE EVALUATIONS — ETHICS, LAW AND POLITICS

Our technology assessment was a pluralistic procedure. The participants represented a broad spectrum of political interests and frequently held contradictory views. Nevertheless, our numerous discussions concentrated on scientific controversies rather than political or ethical differences. Participants argued more about the relevant empirical facts than the criteria of normative evaluation. The focus on scientific evidence was criticised. However, it can hardly be blamed on the procedure of the technology assessment; rather, it is a consequence of the way in which the conflict over herbicide resistant crops had been framed by opponents and proponents in the assessment procedure and in the public arena.

Within this framing opponents claimed that herbicide resistant crops imply considerable risks for human health or the environment, and yield no appreciable benefits. The proponents, in contrast, denied that there are any specific risks and envisaged clear benefits from the technology because weed control in agriculture will become environmentally more friendly, more flexible and more profitable. Both sides in this conflict appeal to political and ethical values (especially health, ecological stability, food supply) which are enshrined in social consensus and therefore cannot really be disputed. Dispute arises over the empirical statements on which both sides base their claims: Can unexpected toxic substances be metabolised in transgenic plants? Could the same also occur with conventionally bred plants? If herbicide resistance genes escape to wild populations, will this have impacts on the natural ecosystem? Will the total amount of herbicides used decrease when nonselective herbicides are available? And so on . . .

It was agreed among all participants in the technology assessment that answers to such questions (including the question whether an answer is at all possible) would not depend on political or moral evaluation but on scientific argument. In accordance, expert reports and discussions centred on these arguments; therefore, preoccupation with scientific issues was inevitable in the technology assessment. It could only have been otherwise had the parties declared right at the beginning, that, contrary to what they say in public, risks and benefits are no important points in the conflict over herbicide resistant crops. Apparently no side was prepared to make such a declaration.

Scientific discussions leave the problems of normative evaluation unresolved. Is the genetic manipulation of plants morally acceptable? Should the spread of herbicide resistance to wild plants count as damage? Who bears the burden of proof for risks which may be hidden or unknown? Is it legitimate to compare the risks from transgenic and nontransgenic plants? What is a relevant benefit? How can risks and benefits be weighed against each other? Should socio-economic need be a prerequisite for the approval of transgenic plants? These are the questions to which discussions will shift once empirical controversies are either resolved or reach an impasse.

Normative discussions do not start at zero. All the issues mentioned have already been covered by existing regulations in one form or another. But, existing law is only the starting point; it is not the ultimate criterion of normative evaluation in a technology assessment. The very fact that a technology assessment operates at some distance from the true process of decision making means that it can and should be used as a forum where one can raise issues of legal and constitutional change, or propagate the reformation of moral standards if that is deemed necessary for coping with the problems posed by a new technology. Our technology assessment was occasionally transformed into such a forum, although consensus was rarely achieved.

The basic normative problem underlying all the discussions is how to deal with new technologies. What is the appropriate response to the challenges of technical innovation? This is by no means a new problem. Since the advent of modern societies, people have been continually burdened with having to adapt to new technologies. In every epoch, resistance was endemic; people have always complained that the speed of technological change and the pressure it imposes on their way of living has truly become unbearable. However, the fact that a problem is old does not mean that it has been resolved in any way. There is no reason to belittle the worries, uncertainties, and objections which new technologies generate today. Solutions which may have been appropriate in the past can fail today if innovation is piled upon innovation. The question whether modern societies have already developed appropriate methods and regulations for dealing with the technological dynamics they have unleashed can never be put at rest. The current controversies surrounding genetic engineering may be taken as evidence of this.

If the discussions in our technology assessment are taken to reflect the level of awareness of people in general, they reveal that the range of views on how society should react to the challenges of a new technology is really not very broad. This range includes outright moral rejection, regulation of tangible risks, questioning the social need for a new technology and the demand that decisions on major innovations be transferred to democratically controlled political bodies. These positions correspond broadly to what will be considered in detail below.[79]

A correct account of the normative discussions in our technology assessment must document the differences in judgement among participants. This will not exclude a critical analysis of the implications and problems associated with various stances: What are the criteria for the judgements? Are they consistent with other accepted values? What are the implications for comparable cases? What else would need to be regulated if the proposals were adopted? In contrast to the scientific claims raised by the participants, no attempt has been made to integrate the various normative claims and derive overall "conclusions". Participants agreed that the final judgement of transgenic herbicide resistant crop plants should be left to observers of the technology assessment and to political decision makers. And one can foresee that normative disagreements which were irreconcilable in our technology assessment will be mirrored in the on-going public controversy in our society. The technology assessment displayed considerable "judicial restraint". But there would seem to be no alternative. Unlike empirical issues, disputes over value judgements cannot be said to have one correct solution which must, in principle, be reached by everyone when arguments are exchanged in a true discourse. There remains scope for dissent. The real issue in dealing with questions of evaluation, therefore, is not how to produce normative agreement within society, but rather how to produce legitimate decisions despite disagreement.

[79] Specific recommendations for regulations are dealt with in section III E below.

A IS THE GENETIC MODIFICATION OF PLANTS ETHICALLY PERMISSIBLE?

There is consensus in our society that we have a moral obligation towards nature. Technological intervention should not call into question the "sustainable" use of nature, or threaten the survival of human beings. Nature conservation, protection of species diversity and commitment to the long-term stability of ecosystems are not just arbitrary political preferences. They are necessary conditions for the survival of humankind and, therefore, have the status of moral imperatives. Moral obligation is based on human interests and rights for the present and for future generations. This is an anthropocentric view: We must respect nature "for our own sake".

Anthropocentric ethics represents the uncontested minimum of moral standards in our society. It rules that we are responsible for the consequences of our actions; "Do not harm!" is the prime duty. On this view, genetic manipulation of plants is not morally permissible if it entails unacceptable risk for humans and the natural resources on which we depend. On the other hand, in the absence of such risk, genetic manipulation becomes morally neutral. On the basis of anthropocentric ethics, then, there can be no *a priori* moral objection to transgenic crop plants.

Public debate on genetic engineering has, however, thrown up more radical moral issues. Is it permissible to engineer living beings like machines? Should humans have the right to break the barriers natural evolution has erected for the reproduction of organisms? Do we owe respect to nature "for its own sake"? If substantive moral objections to genetic engineering can be raised at this level, then the need to examine risks becomes superfluous. Such objections concern the very act of intervention into nature, rather than its further consequences. Proponents of this view sometimes postulate new moral goods which demand our unconditional respect, such as the "integrity of evolution". Ethical reservations of this kind also had a role in our technology assessment. In the discussion of the expert report on ethical aspects of the genetic modification of plants[80], participants considered

[80] Expert report commissioned from Prof. G. Altner (Institut für Evangelische Theologie, Universität Koblenz): "Ethische Aspekte der gentechnischen Veränderung von Pflanzen"; commentary by A. Stanger (Zentrum für Ethik in den Wissenschaften, Universität Tübingen), in: *Materialien zur Technikfolgenabschätzung, Heft 17* (see appendix).

whether the production and release of transgenic crops would be morally impermissible from the point of view of a ”biocentric” ethical view, i.e. one which demands respect for nature for its own sake.

1 Is genetic engineering of plants incompatible with the moral respect we owe nature ”for its own sake”?

Even if one accepts the moral perspective of biocentric ethics, it is still by no means obvious why the transfer of herbicide resistance genes to crop plants should be absolutely unacceptable. Günter Altner argues that humans are obliged to keep an

> ”acceptable balance between respecting the self-purposiveness of nature and subjecting nature to human interests”.

He sees four reasons why transgenic herbicide resistant crops could be ethically unacceptable and calls for a moral halt to the technology ”for the sake of plants” if gene transfer

- has adverse effects on the physiological stability of the plants,
- disturbs the normal interaction of genes in the host species,
- causes irreversible changes in communities of organisms and ecosystems, or
- seriously shifts evolutionary parameters.

Points 3 and 4 concern the consequences of the introduction of transgenic crop plants; these points must be taken into account on a nonbiocentric (anthropocentric) moral view as well, under the heading of risk prevention. In any case, one must bear in mind that herbicide resistance genes offer no selective advantage in natural habitats and hence are not likely to have noticeable effects on the evolution of species and ecosystems. The first criterion is truly biocentric since it appeals to the integrity of the plant as a moral value. We need not discuss whether such a value should be acknowledged, since it is questionable whether it could at all be violated in the case of genetically engineered herbicide resistant crop plants. Apparently, the transfer of resistance genes has no adverse effects on the physiological stability of a plant. Field trials show that the transgenic plants clearly ”thrive” under the conditions necessary for cultivating crop plants. Of course, it could be argued that the plants do indeed lack physiological stability because they cannot survive under natural conditions, i.e. without being tended by cultivation. But were this ethically relevant, one would have to reject crop plants in general as morally unacceptable.

One can perhaps apply the moral obligation to ”respect the integrity of plants” to the species level; but even this still fails to reveal a credible moral objection to genetic engineering in plants. The existing spectrum of natural species is clearly not affected by the transfer of genes to individual crop plants and the propagation of these plants for cultivation. Gene transfer supplements the crop varieties available in agriculture. But crop varieties have always been adapted to suit human needs and, to this extent, they are ”unnatural”. Even if one would go so far as to assign crop plants a ”right to their own evolution”, such a right would not be violated by the introduction of additional crop varieties in agriculture, in this case, resulting from genetic modification. A ”right to one’s own evolution” cannot possibly imply the right that no other new species (crop varieties) be introduced alongside. New crop varieties may displace old ones in agricultural fields and, in the longer term, perhaps at breeding stations. But if this contravenes our moral obligations to nature, then, logically we must proscribe conventional breeding of new varieties just as much as genetic engineering.

From a biocentric point of view, a valid moral argument against transgenic herbicide resistant crop plants can be derived if one adopts Altner’s second criterion: the transfer of genes across species barriers would not be permissible because it interferes with the natural balance of genes in the host species. This view rests on the premise that this balance is itself a moral good and that therefore respect for nature would prohibit us from using human technology recombine what natural evolution has separated. Whether such a premise can in any way be grounded on ethical principles remained an open question in the technology assessment. It seemed that those who adopted this view could only try to convince others by appealing to some common moral intuition.

Many of the participants in the technology assessment could not respond to this appeal. They simply failed to see why a bacterial gene in a crop plant should call the intrinsic value of the plant into question and, in a way, offend its dignity. Undoubtedly, genetic engineering permits more genetic variability in plant breeding than would otherwise be available for the natural evolution of the plant. But the same applies for a number of other breeding techniques (e.g. mutagenesis) which have been used without raising moral objections. Why should we adopt a rule stating that the natural barriers for the evolution of plants also constitute moral barriers for the breeding of plants? Whether crop varieties are natural, in the sense that they could also have evolved without human intervention, or whether they could compete successfully under the conditions of natural evolution was never a moral issue. The fact that a technique is ”unnatural” is not normally a sufficient reason to reject it on moral grounds.

2 ”Genetic pollution”, evolutionary impact, and moral harm

Strictly speaking, the question whether interference with natural evolution is morally admissible does not refer to the evaluation of transgenic crop plants as such, but rather to the consequences the cultivation of such crops could have on other organisms. It is obvious that the consequences must be assessed in terms of implied risks, for example, to ecological stability or the maintenance of species diversity. Sometimes, however, the fact that such consequences exist at all is held to be a sufficient ground for moral rejection of transgenic crop plants—whether or not any risks are implied. This view is based on the premise that any impact on natural evolution is in itself morally harmful. This position was occasionally adopted in the technology assessment: for example, a number of participants believed that relevant damage had already occurred if transgenes had escaped from crop plants to other organisms in which they would not normally be found and to which they could not be transferred naturally. This was denounced as ”genetic pollution”. Furthermore, they considered it an unacceptable ”evolutionary risk” should transgenic crop plants in any way change the conditions of future processes of species formation (e.g. by outcrossing transgenes).

These views were contradicted by other participants, for whom it remained unclear why it would be morally harmful if genes found their way into organisms in which they would not naturally occur. These participants criticised the ”genetic pollution” rhetoric because it lacked empirical meaning, and they refused to accept the idea that impacts on natural evolution constitute damage. Since any human intervention into the living world—in particular, shifts in selective pressure, which result from environmental change—constitutes an influence on the course of evolution, the concept of ”evolutionary risk” makes no sense.

It is indeed true that the moral evaluation of human intervention in evolution faces the problem of how to distinguish between permissible and impermissible acts. There seem to be no clear criteria, if we adopt a biocentric perspective and disregard established (anthropocentric) concepts of risk or positive legal standards for nature conservation. In ecological terms, human populations live and reproduce in nature as the dominant consumer species, and they will influence the future evolution of other species and ecosystems, whenever they interfere with the living conditions of other organisms, be it through agriculture, industry or the public health service. Such influence is not only unavoidable. Strictly speaking, it is also irreversible. Even if some particular interferences can be reversed, evolution does not return to its former state. No ethics can demand therefore that we abstain from interventions in evolution altogether or that we denounce these as inherently immoral.

In addition, moral evaluations become embroiled in contradiction, if impacts on the natural evolution of species are only deemed unacceptable when they result from transgenic crop plants, but are held to pose no moral problem when they result from conventional crop plants. There is no reason to suppose that the spread of transgenes will, in general, have more profound effects on evolution than the spread of endogenous plant genes or mutant genes from conventionally bred crop plants. In any case, it is impossible to predict, even remotely, what phenotype of some new natural species might result in the distant future from the propagation of crop plant genes; and it is impossible to predict how this phenotype could interact in a future ecosystem with some future existing species unknown at present. One could anticipate that genetic traits which offer a clear selective advantage would have greater consequences than others. This argument refers solely to the phenotype, however, and it is valid irrespective of whether a phenotype has been produced by genetic engineering or conventional breeding techniques.

There was probably agreement in our technology assessment that it does not make sense simply to equate interventions in evolution with damage to nature or violation of the natural order. Existing species and communities of species in nature remain subjected to evolutionary change. They are not in static equilibrium, nor do they represent an optimum which would be jeopardised should evolution continue. Evolution is a random process (caused by genetic variation and environmental change), and neither the status quo nor the direction of future development are in any way determined or ”ennobled” by an underlying ”purpose” or goal. It is therefore difficult to predicate damage from the mere fact that the status quo might be changed or the direction of future evolution shifted. One participant in the technology assessment commented that evolution itself must be considered a risk, if we adopt the notion that transgenic plants' leading in the long term (hundreds or thousands of years) to the formation of new species and new patterns of coevolution constitutes "evolutionary risk".

The difficulties in specifying operational criteria to distinguish between morally permissible and morally impermissible human intervention in evolution are obvious and unresolved. But this does not mean that the underlying questions are pointless. We usually avoid the problem by adopting an anthropocentric perspective in which we refer to the interests and needs of human beings. Thus intervention in evolution is clearly not permitted, if it would endanger the stability of the global climate, for instance, or reduce the level of biodiversity which we need to survive (or which we want). Such evaluation avoids the more radical moral issue of whether any intervention in evolution is permissible as long as it does not harm human interests and rights. This question remained open in our technology assessment, but its legitimacy was not disputed. No one argued that any and every intervention in evolution should be tolerated merely because the moral limits were so difficult to define. It may be that fundamental issues about our attitude towards nature come into play in this debate, over which opinions and feelings are deeply divided. What does seem clear, however, is that "respect for nature" is not yet an operational criterion, because there is no inherent goal of evolution in "nature" to which we could refer for guidance. In the final analysis it will always remain necessary to resort to cultural and political criteria, i.e. to criteria of human choice. The limits to human intervention in nature cannot be derived from nature itself, but only from human interests in nature and from the standards we set for dealing with nature properly. Conflicts over these interests and standards will then reflect the underlying diversity of fundamental moral attitudes towards nature in our society.

3 The impositions of ethical pluralism

As soon as ethical criteria above and beyond the prevention of harm to human interests and rights are applied, there will be as little consensus in society at large, as there was among the participants in our technology assessment. We must expect that moral judgements on the admissibility of genetic engineering in general—and transgenic herbicide resistant crops in particular—will remain divided. Some people will find that science should not put together what natural evolution has put asunder. Others will see no ethical problem when genes are transferred across species boundaries to crop plants (nota bene: as long as the possible risks involved in the transfer are not at issue). There appears to be no way to mediate between these conflicting evaluations. We may well have reached the point where differences in the perception and judgement of moral issues are irreconcilable. What does this imply for the evaluation of transgenic herbicide resistant crop plants?

The first requirement is that differences in moral views be taken serious and dealt with properly in society. Perhaps the technology assessment we organised could itself be a kind of model in this respect. It proceeded from the assumption that the conflicting judgements had to be discussed and mutually acknowledged as valid moral views. Indeed, a synthesis of respect and tolerance must surely be necessary for a plurality of irreconcilable ethical convictions to be accepted and to coexist peacefully in society. Beyond the well-founded, minimal ethical standards based on the postulate, "Do no harm", which are generally enforced in our society by the rules of law, individuals should be entitled to live their own lives according to their own values. What they cannot expect, however, is that their own moral views be adopted by everybody else. The impositions of pluralism are that people must accept or at least tolerate the fact that, in a modern society, values which they consider ethically well-founded and absolutely binding are regarded by others as mere preferences to take or leave according to interest and taste.

The verdict on transgenic plants, which can be formulated from a restrictive biocentric ethical perspective, is not entirely without public support; but it is still a particularistic or group ethic. The moral consensus in our society is less restrictive. When dealing with (nonhuman) nature, the only things which are clearly morally proscribed are interventions with unacceptable harmful effects for humans (with some extension to higher organisms in the special case of animal protection). General moral judgement of a technology is thus based on the direct or indirect consequences for humans, and not on the type or the intensity of the interference with nature, i.e. the degree of unnaturalness of the technology. As long as this remains the dominant view, it is difficult to imagine that a moral position which views the transfer of genes from other species as ethically "harmful" and hence strictly illicit could become the basis for collectively binding legal regulation. At the level of regulation, restrictive ethical codes which go beyond the moral, "common sense", cannot be taken into account by appealing to moral grounds. Rather they become downgraded, so to speak, to the status of legitimate group interests which must compete with other interests, and may or may not find a majority in the political process.[81]

Redefining and shifting conflicts from the confrontational arena of ethical conviction to the competitive arena of group interest is an important mechanism for peace-making in differentiated, pluralistic societies. However, this mechanism will only work if no values are at stake which are considered fundamental and sacrosanct. In the case of transgenic herbicide resistant crop plants, the danger of moral polarisation is not particularly great. While a strict stance against any transfer of genes across species barriers may be morally valid, the engineering of plants is not exactly predestined as a topic of fundamentalist conflicts of belief. In our technology assessment, no one went so far as to accuse those who did not share their particular moral views of being ethically blind and irresponsible. Even in a biocentric ethical view it is still possible to suspend ”respect for nature”, if there are good reasons for doing so. In each case, it will be necessary to weigh agricultural considerations or economic considerations and also advances in science, to determine whether there is indeed sufficient justification to ignore ”respect for nature”. And, such deliberations always tend to work against the rise of fundamentalism in moral belief.

B ARE THE RISKS OF GENETIC ENGINEERING ACCEPTABLE?

The novelty of genetic engineering raises fears, and criticism of risk is the most common political manifestation of these fears. Discussions in our technology assessment over the possible risk of genetically engineered crop plants went through various stages with which we are already familiar in the public debate over genetic engineering in general. The discussions proceeded as follows:

- from recognisable risk with predictable consequences to the hypothetical and to unknown risk with unforeseeable consequences: Should we regulate imaginable risk or risk that we cannot, in any case, exclude with certainty?
- from the isolated assessment of risk involved in genetically modified plants to a comparison of risk between transgenic and nontransgenic plants: Are there specific risks associated with genetically modified plants, which do not arise with conventionally bred plants?
- from the need to substantiate suspected risk to the reversal of the burden of proof: Should freedom from any and all risk be demonstrated before a new technology can be introduced?
- from arguments over risks to arguments over social benefits and needs: Are uncertainties with respect to risks only acceptable if there is a real and significant social need for the technology?

Going through these stages of debate is both typical and necessary. It reflects the logical order which the criticism of risk will follow when put to the test of argumentation. Throughout the course of the discussions, both proponents and critics of genetic engineering were confronted with empirical findings they could not avoid. Empirical findings do not, by themselves, force a revision of political assessment; but they may force people to reconsider and eventually modify or replace the reasons for their assessments. As a result, new normative issues will be brought into play, which raise the conflict onto a different plain. The following sections summarise the transformation of risk discussion in our technology assessment, starting from imminent, recognisable risks and culminating in restrictions based on diffuse, unsubstantiated fears that may be induced by the sheer novelty of genetic engineering.

1 Recognisable risks of transgenic plants: unexpected metabolic changes, feral populations, horizontal gene transfer

New toxic or allergenic substances in plants. No participant of our technology assessment contested the notion that unexpected toxic or allergenic metabolic products represent a relevant risk which must be regulated at least for food and fodder crops. For transgenic herbicide-resistant plants three possible risk mechanisms are clearly identifiable. (1) Detoxification of the nonselective herbicide in the resistant crop plant can result in toxic metabolites of the herbicide being formed. (2) The gene product introduced via gene transfer can itself be toxic. (3) Gene transfer (and the introduction of the gene product) can activate or increase the level of toxicants typical for a given crop species (for instance, alkaloids in potatoes). It is also conceivable that some known allergenic potential would increase, i.e. that the host plant could become a

[81] If the law ignores the moral beliefs of some segments of society, it will only be acceptable if it is based entirely on the principle of legitimation by majority decision and if it refrains from any judgement about the validity of overruled moral beliefs. Political battles nevertheless tend to provoke appeals to moral fundamentalism; consider, for instance, the rhetoric used in the referendum campaigns against transgenic organisms in Austria and Switzerland.

more potent allergen as a result of plant metabolic interaction with the transgenic gene product. And it is conceivable that a known allergenic potential in the donor organism be transmitted to the host plant through the transgene.82

While there was consensus that these risks must be regulated, it was also pointed out that they are not specific to transgenic plants: they can also occur in crop plants which have been modified using conventional breeding techniques (see above, section II, A1). The real issue was, therefore, how far such the tests should go and whether there are nevertheless good reasons to regulate transgenic plants more strictly than conventionally bred crops varieties (see below, section III E1).

Feral populations. Much the same arguments were applied with respect to the risk that feral populations of herbicide-resistant plants might be formed. There is a recognisable risk that a domesticated transgenic crop could run wild, i.e. that it ”escape” from cultivated areas or that it could propagate the transgene to related wild plants through hybridisation—if suitable reproductive partners were available. But these mechanisms apply equally to transgenic and nontransgenic cultivars. Furthermore, the possible harm that could result from feral herbicide-resistant plants does seem to be limited. Such plants could become weeds in agricultural systems, which would then imply financial loss for the farmer and, more significantly, for the herbicide manufacturer who, in turn, would lose a market for the nonselective herbicide. Feral populations could also result in a temporary increase in herbicide load on the field—for instance, if farmers attempt to kill resistant weeds by increasing herbicide dosage or number of herbicide applications. It seems unlikely, however, that feral populations would pose any ecological threat to natural habitats. Wild plants which develop herbicide resistance through hybridisation with resistant crops will not be more competitive, since herbicide resistance offers no selective advantage outside the area where the matching herbicide is applied.

Horizontal gene transfer. Herbicide resistance genes can be proliferated from transgenic plant cells to soil bacteria through horizontal gene transfer. Although such transfer can also occur with endogenous plant genes from nontransgenic plant cells, the transfer rates would be higher theoretically for certain transgenes—depending on the gene construct. In any case, horizontal gene transfer will probably occur only rarely. If it does, and if the resistance genes find expression in the soil bacteria, a foreseeable consequence would be selective growth of these bacteria, so long as a matching herbicide is applied; the growth would be confined to those parts of the soil where the herbicide is effective (usually close to the soil surface). In addition, the transformed bacteria could influence soil chemistry by releasing metabolic products which did not previously exist in the soil in this form.83

Since it was agreed that horizontal transfer of genes from herbicide-resistant crops cannot be excluded, the question whether the effects we could expect should be considered environmental damage became a crucial point of discussion. Many participants denied that any damage would result. In particular, it was pointed out that many farming activities, such as crop rotation or fallowing, induce significant changes in soil chemistry, and that mechanical weed

[82] This apparently happens when the gene coding for 2S albumin in the Brazil nut is transferred to the soybean (Nordlee *et al*., 1996). It should be noted that this finding, although new, has by no means come as a complete surprise. The Brazil nut is a known allergenic food. That 2S albumin could transfer allergenicity to soybeans is a clearly identifiable risk. It goes without saying that such risk must be tested for and excluded (see FDA, 1992). In the present case, the tests were carried out by university researchers in cooperation with a seed company, Pioneer Hi-Bred, in the early phase of developing the transgenic soybean, i.e. well ahead of the testing required for the approval of transgenic products.

[83] This summary of the discussion in the technology assessment was criticised by one of the participants:

> ”The text unfortunately fails to point out that in particular the nonselective herbicides glufosinate (Basta) and glyphosate (Round-up) and their derivatives are effective against bacteria and fungi, so that horizontal gene transfer under this selective pressure would be considerably enhanced.”

Whether glufosinate and glyphosate actually do exercise greater selective pressure on bacteria and fungi than other certified herbicides requires closer examination. The expert report by Wilke on the effects nonselective herbicides have on the soil concludes tentatively that this is not the case, in: *Materialien zur Technikfolgenabschätzung, Heft 7* (see appendix); see also the statement by Dr. J. L. Honneger (Monsanto): ”Factors for Consideration Regarding Glyphosate Tolerant Crops”, in: *Materialien zur Technikfolgenabschätzung, Heft 6*, pp. 90-93; and section II A2 above. On the basis of this finding, it seems reasonable to assume (as in the discussions of the technology assessment) that whether horizontal gene transfer from transgenic herbicide-resistant crops is more likely than from nontransgenic plants depends primarily on the gene construct. Incidentally, selective pressure resulting from the anti-microbial effectiveness of nonselective herbicides was one of the presuppositions in our technology assessment; otherwise we could not have considered the accumulation of resistant bacteria and changes to soil chemistry as possible impacts of gene transfer.

control, in particular ploughing, also leads to massive fluctuation among populations of soil microorganisms. None of these effects have ever counted as environmental damage. Selective growth and temporary increase of herbicide-resistant populations of bacteria in soil can also be expected when selective herbicides are applied to nontransgenic crops, because naturally occurring resistant mutants are selectively favoured. That soil functions could be impaired is not a very realistic expectation. The impact of herbicides on soil is tested before approval of a herbicide is granted. Herbicides which permanently eliminate nonresistant soil bacteria will not pass these tests; this also applies in the case of nonselective herbicides.

The risks from transgenic herbicide-resistant crop plants described so far would not seem dramatic, were they compared to the risks from conventionally bred crops using well-established techniques and practices. Basically no risk from transgenic plants was identified in the technology assessment that was not already known from nontransgenic plants. Recognised risks seem to ”normalise” through comparison. At this point the debate in the technology assessment moved one stage further, from recognised risk to hypothetical (i.e. suspected or unknown) risk.

2 Focusing on the lack of knowledge: the risks of ignorance, uncertain prognoses and the limits of testing

The main argument against normalising risks through comparison was that an assessment must not be confined to recognisable risk which can be described and tested. The real risk from transgenic plants lies in the fact that we do not yet know exactly what all the risks are. We can neither foresee all the possible consequences of transgenic herbicide-resistant plants, nor control them through preventive testing. And we cannot, therefore, rule out physiological and ecological impacts of transgenic crops, which are different from those we know from nontransgenic crops.

The basic premise of this argument was uncontested: Our knowledge is limited. There is no way to predict all the possible effects of transgenes on plant metabolism nor to rule out the presence of toxic or allergenic substances that we have not or cannot observe in the host species. Nor can we eliminate these risks completely by extending the certification tests. We do not know all the substances in plants, nor can we test for them all. Similar uncertainties exist with respect to environmental consequences. It is not enough to assess the ecological impacts of a single, transmitted trait (herbicide resistance); the transfer of herbicide resistance genes could have unexpected side-effects on the plant metabolism, which affect the plant phenotype and possibly expand its ecological range, i.e. increase its fitness. Such impacts will not necessarily be revealed through the testing required for the approval of new cultivars, so long as they do not impair breeding goals. It is also impossible to predict what impacts herbicide resistance genes transmitted to wild species through hybridisation could have on the evolution of natural species and habitats in the long run and under changing ecological conditions. Finally, it is difficult to refute the theoretical possibility that bacteria transformed through horizontal gene transfer from herbicide-resistant plant cells would release substances into the soil, significantly different from and more harmful than new substances which might result from changes in crop husbandry or from the use of new herbicides.

While it was generally admitted in the technology assessment that uncertainties exist which cannot be resolved, participants disagreed about how the uncertainties should be dealt with. Do they constitute a sufficient reason to ban transgenic herbicide-resistant crop plants? Critics of the technology deemed this conclusion compelling, invoking the principle of precaution which requires that risk be minimised. For them, uncertainty of prognosis was not only an unavoidable risk, but an unacceptable one. The proponents of transgenic herbicide-resistant crops, on the other hand, rejected this conclusion. They argued that unforeseeable consequences must always be expected, and that uncertainty of prognosis also applies to conventionally bred plants, without ever being considered sufficient reason to ban such plants.

Breeders have, in fact, never been able to predict what the physiological impact of new genes might be or to control them, given the genetic background of the host plant. ”Surprises”, i.e. unexpected or undesirable side-effects (pleiotropy) are abundant in conventional plant breeding; they must always be dealt with *ex post facto* through testing to select those examples which are suitable for being further developed into new crop varieties. The testing process is necessarily limited. One can never screen all plant substances to detect changes which might be toxicologically relevant. Phenotypic changes in new plants will be identified through selection procedures only if these changes are undesirable in terms of breeding goals. On the other hand, other changes which may still be ecologically relevant (like increased stress resistance) could go unnoticed. With respect to long-term impacts on the evolution of species and ecosystems, one can only say that they are as indeterminate and unpredictable for conventionally bred plants as for transgenic plants.

As a result, comparison to conventionally bred plants not only tends to ”normalise” the recognisable risks from transgenic plants, it also tends to normalise the uncertainties involved in such plants and the hypothetical risks that may be derived from the fact that we have limited foresight of the possible consequences of such plants. This defeats the main public argument against transgenic plants, namely, that such plants will present us with new, specific risks. Not surprisingly therefore, the question of whether the comparison between conventionally bred and transgenic plants is legitimate became a central focus in our discussions.

3 Are risk comparisons legitimate? The ”special quality” of genetic engineering

Risk comparisons were commonly used in the debate over transgenic crops.[84] They suggest themselves as a general method of evaluation for normative issues. Since levels of acceptable risk cannot be objectively determined, an obvious approach would be to refer to what has actually been accepted in comparable cases in the past, and to consider if there are any reasons to deviate from this model. The underlying assumption is that comparable risks should be treated comparably, but this need not be the case. It is also possible to decide that the risks from a new technology should be regulated more strictly than comparable risks from a well-established technology with which we are already familiar. In this case, ”novelty” would be the main criterion for such regulation.

Comparing risks will in general be regarded as legitimate as long as the risks are indeed comparable. However, the criteria of comparability are controversial. Arguments, for instance, which compare voluntary and involuntary risks are not considered conclusive. The same holds for the comparison of dread risks, which could inflict sudden catastrophe, and diffuse risks, where damage slowly accumulates slowly, resulting from a series of scattered events.[85] Obviously, no such pitfalls exist when the risks from transgenic and nontransgenic crop plants are compared. Moreover, in our technology assessment, the legitimacy of this comparison is confirmed *prima facie* by the fact that it was the critics of genetic engineering who put it on the agenda. The report commissioned from the Öko-Institut refers explicitly and repeatedly to the problems, risks, side-effects and uncertainties known from conventional breeding, in order to demonstrate what could happen with genetically engineered plants. This approach invites the claim to the contrary that, if the criticism is valid, then it shows, at the same time, that the risks and uncertainties from transgenic plants are the same as those from nontransgenic plants. To escape this conclusion, critics must dispute the comparability of transgenic and nontransgenic plants, and show that genetic engineering makes a difference. Two arguments were used in the technology assessment to prove the ”special quality” of genetic engineering:

(1) Genetic engineering allows the transfer of genes across species barriers. Hence metabolic pathways can be introduced into a host plant, that have never belonged to that species and could not have been acquired through natural evolution or conventional breeding. Such new pathways constitute a specific factor of uncertainty; therefore the risk of uncontrollable physiological or ecological side-effects (pleiotropic effects) is higher with transgenic plants than with new conventional plants.

(2) The transfer of genes through genetic engineering disturbs the genomic context of the host plant. Transgenes are inserted at random in the genome. Therefore, positional effects (insertional mutagenesis) must be expected, that can induce changes in the traits of the transformed plant, which are unrelated to the information coded in the transgene and hence cannot be foreseen.

In our technology assessment and in the German public debate these were the key arguments used to support the claim that transgenic plants pose higher risks than new plants produced by conventional breeding techniques. These arguments refer to the suspected or hypothetical risk that there might be more severe unexpected side-effects from transgenic than from nontransgenic plants. There is no empirical evidence as yet that more side-effects do in fact occur; nor can theoretical models be invoked to elaborate this hypothesis in any detail. However, as one critic put it, one can infer from the ”special quality” of genetic engineering that a ”special type of uncertainty” is implied by transgenic plants and, hence, an additional factor of risk. This argu-

[84] See OECD (1993).

[85] Even if the absolute amount of damage (in terms of lives lost) is the same in both cases; see Slovic *et al.* (1985); Slovic (1987).

ment is designed to refute the comparative "normalisation" of risk by claiming that transgenic and nontransgenic plants are, in fact, not comparable. At the same time, however, it implicitly confirms the validity of the comparative approach in principle: if the "special quality" of genetic engineering cannot be demonstrated, then the comparison to conventional crop plants remains legitimate; the assumption that transgenic plants constitute a specific risk becomes unfounded.

In our technology assessment it was not possible to defend the notion that disturbances in the genomic context (and positional effects) constitute a "special quality" of genetically engineered plants. Such disturbances also result from conventional breeding techniques or when naturally occurring transposable elements (transposons) move around in the plant genome. Transposons, too, are inserted at random. No reasons were given why context disturbances in transgenic plants should be different. At the end of the discussions, context disturbances, too, were "normalised" through comparison, and the argument that these disturbances demonstrate the "special quality" and special risks of genetic engineering was invalidated.

On the other hand, the argument that the introduction of new metabolic pathways unknown in the host plant constitute a special risk factor, was declared as valid in principle. Once again, however, the argument was relativised by comparisons. While it is true that the probability of side-effects is theoretically higher for transgenic plants, whenever new metabolic pathways are transferred, it is also true that the probability of side-effects is theoretically higher for nontransgenic plants because, when these plants are crossbred, an uncontrolled number of undetermined genes is exchanged, all of which can interact with the existing plant metabolism (in contrast to genetically engineered plants, where only one, exactly identifiable gene product is transferred). No method exists to balance these two countervailing factors. Since the argument is about hypothetical but undetermined and unpredictable side-effects, quantitative probabilities are unknown. In the final analysis, then, the claim that there will be more physiological side-effects with transgenic plants is not better or worse than the claim to the contrary that there will be fewer such side-effects. Neither hypothesis can be confirmed or refuted.

It would seem, therefore, that opting for one or the other of these hypotheses as a basis of our risk assessment is merely a matter of political preference. It should be noted, however, that theoretically fewer side-effects are to be expected from transgenic than nontransgenic plants, if the gene transfer introduces metabolic pathways which are already established in the host plant species.

4 Reductionist versus synergistic risk philosophy?

In Germany, the public debate over genetic engineering has frequently been framed as a battle of competing risk philosophies. The dominant regulatory approach concentrates on the gene (gene product) to be transferred and considers the function of this gene in the donor organism in order to assess the risks of the gene transfer: "It is the gene that matters". Critics have rejected this approach as an unacceptably reductionist view of the problem. They emphasise that the effects of transgenes depend on the genetic background which they find in the host organism. Therefore the effects cannot be derived from knowledge of the gene sequence and of the gene function in the donor organism: "It is the context that matters".86

This controversy did not have a prominent role in our technology assessment, since consensus was reached on the following points:

- The coding information of a transgene depends on the gene sequence and not on the context of the gene, which means, that the site in the host genome to which the gene is transferred has no influence on the type of gene product that can be formed.
- Transgenes coding the information for a gene product which induces toxic substances in the donor organism or enhances its fitness pose greater risks than transgenes for which no such effects have been identified.
- Transgenic gene products can have effects in the host organism, which result from interaction with the existing plant metabolism and therefore cannot be derived from the information encoded in the transgene or from the gene function in the donor organism.
- The locus of integration of the transgene can influence the expression of the transgene or of neighbouring endogenous plant genes. This may also have impacts on the host organism, which cannot be derived from knowledge of the genetic information of the transgene or its function in the donor organism.

These points shed doubt upon the formula, "It is the gene that matters". While they still support the notion that one must consider whether the specific gene construct to be transferred poses

[86] Cf. Kollek (1988). the Öko-Institut Freiburg adopted these arguments as the basis of its expert report.

any known risks in the donor organism, they also show that such consideration is not enough to anticipate the effects the gene might have in the host organism. Therefore, it is not only the gene that matters, the context matters as well.This conclusion was not controversial in the technology assessment. Participants implicitly agreed that there are some reasons which support a synergistic risk philosophy. They disagreed, however, about whether these reasons warrant specific regulation for genetically engineered plants. If it is true that all breeding techniques can induce unforeseeable metabolic changes (pleiotropic effects) and disturbances of the genomic context (insertional mutations) in crop plants, then reference to synergistic risks in transgenic plants is clearly legitimate but not at all sufficient to mark a real difference from nontransgenic plants which have been modified by conventional techniques. It was the question of whether and how a difference can be established, that dominated discussions in the technology assessment, not competing risk philosophies. And in dealing with this question the critics had to resort to ever more remote hypotheses about the specific risks of genetically engineered plants.

5 From hypothetical to speculative risks

All participants agreed that the assumption of specific risks which may be involved in transgenic but not in conventionally bred crop plants must be substantiated if it is to be taken seriously into account. The expert report from the Öko-Institut attempts to do just that. In general, reference to the novelty of genetic engineering is not considered sufficient to substantiate suspected risk. The critics suggested various risk hypotheses which differed in their degrees of elaboration.

The hypothesis that transgenic plants pose specific risk in terms of physiological side-effects seems relatively well-founded. A plausible mechanism is described for this postulated risk: It is possible that the transgenic gene product metabolises other substrates and hence has a different impact in the host plant than in the donor organism. The probability of this will be higher in transgenic than in nontransgenic plants if genes are transferred which code for a product that was never in the plant metabolism before.

On the other hand, the hypothesis that genetic engineering might involve specific risks *per se*, which exist irrespective of what the gene product is, seems rather weak. No mechanism was proposed for such a risk. The standard argument advanced in the German debate was the ”special quality” ascribed to genetic engineering because of context disturbances and positional effects resulting from the insertion of transgenes. If one accepts that the comparison with transposons, chromosome translocations or chromosome breaks occurring in nontransgenic plants refutes this argument effectively, it remains a mystery why gene transfer should be able to cause more or different unexpected side-effects in crop plants than changes induced by conventional breeding techniques. The claim that transgenic plants might involve specific risks is reduced to suspicion without foundation.

In our technology assessment discussions, it was proposed that different risk scenarios be distinguished: The term ”hypothetical risk” should apply only if a scenario bases suspected risk on known mechanisms which demonstrate that harmful effects are possible in principle and show how these could arise. The term ”speculative risk” should be used when no mechanism is specified or when a scenario assumes that mechanisms might exist or events might occur which are not yet known. On the basis of this distinction, the claim that transgenic crop plants could involve specific risks solely because they have been genetically engineered must be classified as speculation, not as hypothesis.87

This result tends to justify current trends towards product-based rather than process-based regulation of genetic engineering, i.e. where genes and gene products are assessed, not the methods through which the genes have been transmitted. A good case could have been made against this regulatory approach, if the assumption that genetic engineering *per se* involves specific risks were a well-founded hypothesis; the case is much weaker, of course, if it is merely unfounded speculation. It is therefore understandable that the critics of transgenic

[87] In contrast, the assumption that the introduction of gene products alien to the metabolism of the host plant species might imply additional risk was accepted as a valid hypothesis. One participant argued, however, that this assumption is also just speculation.

> ”That new toxic or allergenic substances will be formed is mere speculation, as long as it is not clear why one should reasonably expect that substrates modified by the gene product could be toxicologically relevant.”

In the case of transgenic plants with resistance to glufosinate (introduction of a specific acetyltransferase), the suspicion would be warranted only, ”if there were some indication that acetylated substances are likely to be toxic or allergenic”. But there are no such indications.

plants in our technology assessment did not simply give in at this point. They insisted that the discussions could, at best, have shown that, on the basis of existing scientific knowledge, the "special quality" of genetic engineering (and hence specific risks) cannot be demonstrated. They argued further, however, that differences between transgenic and nontransgenic plants, which cannot be demonstrated, can nevertheless exist.

This argument replaces reference to an empirical fact, "*genetic engineering has a special quality*", with reference to a logical possibility, *"it is conceivable that genetic engineering has a special quality"*. It seems that this move is no longer an attempt to provide reasons for the hypothesis of specific risks, but rather an attempt to avoid the need for further reasons.

In general, the discourse in our technology assessment proceeded from the premise that, whoever makes a claim must substantiate it. Consequently, those who claimed that the risks of transgenic and nontransgenic plants are comparable had to deliver the arguments. What they did was to show that whatever risk or uncertainty was identified and described for transgenic plants, equivalent risk or uncertainty can be identified for conventionally bred plants. But they were not supposed to demonstrate the impossible, namely, that unknown risks from transgenic plants, which might exist but have not been identified and cannot be described, are also equivalent.

The fact that our knowledge is limited mitigates against those who claim that differences which we do not recognise may nevertheless exist. Logically, lack of evidence does not prove that the differences do not exist (we may find one tomorrow); practically, however, if we find no difference we treat things as being equal (for the time being), not as different. There seems to be no alternative. Where we do not know, we cannot distinguish. This makes an easy argument for those who claim that things are comparable. On the other hand, the concept of equality would lose all meaning if, in the absence of observable differences, things must be counted as different and not as equal, until the contrary were proven.

This rule was apparently accepted, at least implicitly, by all participants in the technology assessment. Otherwise, critics of the technology could have foregone sophisticated arguments to show why genetic engineering has a "special quality" which makes a difference between transgenic and nontransgenic plants. They could have argue instead that even if we do not observe any differences, we can assume that they exist and base our risk assessment on this assumption. Obviously, no one thought this argument to be sufficient. In sum, therefore, the fact that transgenes, as far as their impact on the genomic structure is concerned, cannot be distinguished from transposons and the recombinations that occur in conventional plant breeding precludes the hypothesis that specific risks might be involved just because genetic engineering has been applied.

6 Hypothetical and speculative worst-case scenarios

When we consider suspected risks which might exist but have not been experienced, then, by definition, the possible damage from such risks cannot be foreseen. But is the damage also "unforeseeable", in the sense that anything could happen? Should we assume that the hypothetical risks from transgenic plants could have fatal or catastrophic consequences?

Different worst-case scenarios were discussed in the technology assessment. In terms of specific metabolic risks from transgenic plants, associated with alien gene products, the envisaged damage was that toxic or allergenic plant substances could be formed, making the plants unsuitable as food. If reactions to these substance were severe, the risk would be easy to identify and the respective cultivar could be taken off the market immediately. If the effects were low-level, however, while they may not necessarily be harmless for human health, damage would likely go unnoticed or it would be difficult to attribute to the transgenic food crop as the probable cause.[88]

This worst-case scenario uses empirical examples and theoretical models from plant physiology, plant breeding and food toxicology to circumscribe possible consequences. It relies on known causal mechanisms and does not assume, for example, that harmless crop plants would suddenly begin to produce deadly poisons when a herbicide resistance gene is added.

A cautious approach was also taken to describe the worst case of environmental damage that could result from transgenic plants: Should unexpected metabolic changes lead to increased ecological fitness then, it was assumed, transgenic crop plants could invade agricultural habitats as weeds and cause agronomic problems or yield loss for the farmer. Eventually the plants (or their hybrids with wild relatives) could

[88] See section III E1 below for the testing required.

become established in natural ecosystems and change these. The empirical model for the latter assumption was the undesired spread of nonindigenous or poorly domesticated crop plants such as the American black cherry in German forests, topinambur along rivers, or rhododendron in the British countryside.

Occasionally, however, much more dramatic images of worst cases were proposed in our technology assessment. In a kind of ”thought experiment”, one participant developed the following scenario of how horizontal gene transfer from genetically engineered crop plants could result in ecological catastrophe: Transformed bacteria could release new metabolic products into the soil which induce permanent changes in the composition and function of soil microflora that differ from and go farther than the changes normally induced by agricultural practice. These changes could, if transgenic plants became used on a massive scale, affect the evolutionary balance between bacteria and plants—the basis of the composition and production of earth’s atmosphere. As a result, our atmosphere and climate could be changed significantly.

This thought experiment is revealing because it shows that a catastrophic threat can easily be hypothesised if logical possibilities are compiled one after the other without identifying any mechanism to explain how events which are imagined could become real under suitable circumstances. The above scenario for ecological catastrophe triggered by horizontal gene transfer must be dismissed as mere speculation—it is not a reasoned hypothesis. This stands in sharp contrast, for instance, to the worst-case scenarios discussed in relation to nuclear power. Here, the causal mechanisms that would inevitably lead to catastrophe, provided certain initial conditions are met, are known: for example, a permanent breakdown of all cooling systems. No comparable mechanisms are known for the case of transgenic plants. One would have to postulate them as a hypothesis, that is, assume that hidden mechanisms exist, of which we are unaware, but which operate specifically and only for transgenic organisms and have the capacity to translate small, immediate consequences into large, long-term catastrophe.

7 Regulating suspected risks

There were widely differing views in the technology assessment about appropriate political and legal responses to suspected risk, and this aspect remained controversial. Some argued that while hypotheses of risk might be a proper reason for demanding more research, they should on no account be the basis for additional regulation. Others felt that even speculative risks warrant drastic precautionary measures to ward off possible harm from genetically engineered plants.

The first position outlined above is more restrictive than current policy and law. It is an accepted principle in many fields that precautionary measures can be taken if there are good reasons to suspect risk. It is not necessary to wait until some risk is clearly recognisable and danger imminent. Effective protection of important goods such as life, health, or ecological stability presupposes some response to uncertain risk. This applies in particular when such risks could have catastrophic consequences should they become real. Therefore, it should be no question that some kind of regulation is appropriate in dealing with hypothetical risk.[89] The question is, how restrictive can the regulation be? In general, the assumption of hidden risk from a new technology will justify additional safety measures and controls, but not a complete ban on the technology. In the German law this rule follows from the principle of proportionality. This principle also says that the greater the potential damage from assumed risk, the more restrictive the precautionary measures may be.

The second position outlined above, that drastic precautionary measures always be taken, goes beyond current policy and law in most countries. It implies that any kind of suspected risk is a valid reason to ban a technology, even if that risk can only be described as ”theoretically not to be excluded” (a formula used throughout the Öko-Institut’s report). In this case it would be sufficient that there is a logical possibility that the technology implies hidden risks which we do not know and hence cannot describe in any way. The German Supreme Court had to deal with this kind of uncertainty about risks in the case of nuclear power plants and ruled that it constitutes ”residual risk” which must be tolerated as socially adequate, since the only alternative would be that the state had to ban the new

[89] The German Federal Administrative Court has ruled that, in designing precautionary measures for nuclear power,

> ”also possibilities of harm must be taken into account which cannot be excluded because, given the present state of knowledge, certain causal relations can neither be confirmed nor denied and, hence, there is no clear and present danger, but only suspicion of danger or a potential of worry” (Bundesverwaltungsgericht, Volume 72, 1985: 315).

technology completely.[90] However, the court did decide what the state *must* regulate in order to meet its obligation to protect the basic rights of its citizens. What the state *can* regulate under the precautionary principle is a different question. There is considerable scope for a more restrictive policy.

The German constitution, for example, certainly does not rule out precautionary measures against speculative risk, or regulations that respond to diffuse public anxiety that some unknown evil occur if transgenic plants are released. The early safety guidelines for genetically engineered organisms issued in most countries during the late 1970s (after the Asilomar Conference in 1975) may be taken as an example for the regulation of speculative risk. The guidelines were quite restrictive although the main justification for them was the fact that genetic engineering was a novel technology and that experience was lacking with respect to its possible consequences. Nevertheless, these guidelines would have been permissible as binding law under the German constitution, because they leave some freedom. While they restrict the use of genetically engineered organisms, they do not exclude them completely; the scope of the guidelines envisages that these restrictions could be lifted after a period of testing, if there are still no further indications that the suspected risks in fact exist. It was along these lines that most participants in the technology assessment proposed to regulate transgenic herbicide-resistant crop plants. They recommended some additional safety measures to be reviewed after a specified period.[91] Under German constitutional law, however, it would be difficult to sustain absolute and complete prohibition of transgenic plants on the ground that this would be the only way to eliminate all the conceivable, unknown risks these plants might imply. Such a ban would be incompatible with the basic rights of the parties with an interest in the technology (manufacturers or users).

Therefore, the legal relevance of arguments based on speculative risk is limited. But this may not be a conclusive objection within the context of technology assessment. In principle, it would be legitimate to argue that proper regulation requires a revision of current legal principles, including a redefinition of the balance of basic rights between those who want to use new technology and those who want to minimise its risks. A more serious objection would be that speculative risk arguments are inadequate as criteria of normative assessment because they do not distinguish between what should be allowed and what forbidden. If no justification must be provided for suspected risk, then such risks can be invoked against anything at any time. The same applies to speculative worst-case scenarios. If the fact that we do not know exactly what could happen constitutes legitimate reason to assume that any imaginable consequence might be possible, then we would have to expect catastrophes everywhere all the time, and no innovation could be approved. There is no way, really, to know what can happen with a new technology until it has been tested under real conditions. And even then, we cannot be sure that we have complete knowledge of all the possible consequences. Established technologies, too, may have hidden risks. Therefore, if we are to calibrate precautionary policy and approval of new technologies with a view to the maximum possible harm that can ensue, then speculative worst-case scenarios are useless as criteria.

8 Reversing the burden of proof—*in dubio contra projectum?*

Discussions in our technology assessment suggest that unsubstantiated, hypothetical risks and worst-case scenarios that fail to explicate suitable mechanisms for how damage might occur will have no relevance for the regulation of new technology. But is this conclusion compelling? It was, at any rate, rejected by all those participants who had argued that transgenic herbicide-resistant crop plants should be banned, because the existence of unknown risks could not be excluded. The underlying rationale of this argument seems to be that the burden of proof should be placed on claims of safety, not on claims of risk.

As a rule, the relative safety of a new technology must be demonstrated by passing it through a filter of preventive testing before it can be unleashed on society. But the general legal principle is that the burden of proof lies with those who claim risks. Those who argue that a technology, although it may have survived the testing for approval, is nevertheless still not safe,

[90] Bundesverfassungsgericht, Volume 49 (1978) 143. The Federal Administrative Court requires under the Federal *Clean Air Act (Bundesimmissionschutzgesetz)* that ”there are sufficient reasons to assume that immissions could possibly lead to harmful effects on the environment” (Bundesverwaltungsgericht, Volume 69, 1984: 43). Suspected risk ”on the basis of theoretical considerations and calculations” may be sufficient reason; it is not enough, however, if ”small minority opinions in science propose a theoretical assumption which is falsifiable, in principle, but untestable with the available means” (*ibid.*).

[91] See section III E below.

have to prove that there are additional risks. If they are unable to do so, or if they cannot substantiate suspected risks in plausible hypotheses, they loose their case and the technology is authorised. This principle favours innovation. It is based upon the value judgement that hidden risks and unforeseeable consequences that escape our best efforts of anticipation are a worthwhile price to pay for new technology and the freedom to innovate. Furthermore, it implies confidence in society to be able to cope with such risks and their consequences, should they occur in the future. Apparently, neither broad acceptance of innovation nor confidence in our ability to repair things if they go wrong can be taken for granted in society. And these premises were definitely not shared by the critics of transgenic plants in our technology assessment. They demanded a complete reversal of the burden of proof. Given the fact that herbicide resistance genes cannot be contained or retrieved in nature, the possible harm from hidden risks could be irreversible once transgenic plants are released into the environment. Therefore, it was argued, the release of such plants should not be allowed until it is proven that they involve no additional risk.

Under such a rule any kind of risk assumption becomes a conclusive argument. Remote or speculative scenarios do not have to be justified by the critics of a technology; rather, they must be refuted by its proponents. *In dubio contra projectum!* Consequently, reversal of the burden of proof suggests itself as an ideal strategy to maximise the impact of risk arguments. The question remains, however, whether this strategy is practicable. In particular, two problems were raised: (1) Must we not apply the reversal of the burden of proof to both old and new technology? (2) Will any new technology ever be approved under this rule?

Why should the reversal of the burden of proof apply to new technologies and not to old ones? After all, continued use of an old technology is just as much an experiment involving uncertainties and unforeseen consequences as the introduction of new technology. A pragmatic answer to this question might be that we also treat old and new technologies asymmetrically in other cases. For example, the German law on toxic substances or medical drugs still allows old products which would not be approved according to current standards. In principle, however, such asymmetry discriminates against innovation and favours the technological status quo. This is based on the value judgement that society has little to lose if innovation is slowed down or blocked, and that we are generally better off living with the risks and uncertainties of old technology than with the risks and uncertainties of new technology.

Of course, this value judgement was also controversial. We are not necessarily on the safe side when we opt for the continued use of old technology against innovation. Established practices can also be fraught with unknown hidden risks which we may only recognise later. These, too, could have consequences as severe as any of those unknown risks from a new technology—for instance, climatic changes brought about by the continued burning of fossil fuels. In addition, where we could act, we are not only responsible for what we do, but also for what we do not. Strictly speaking, the precautionary principle would also require that we consider the risks (including hidden risks) we take if we forego innovation and stick to old technology.

A remaining argument in this debate was that those technologies with which we are familiar seem less threatening because we have already had some time to detect their hidden problems and to adapt to them. We have extensive practical experience with conventional breeding techniques, but not with genetic engineering. In this sense, nontransgenic plants indeed fare better in terms of safety levels than transgenic plants (although some so-called conventional breeding techniques may also be new and heretofore untested). The final question would then be whether this advantage is a sufficient reason to prefer an old technology over a new one. Opinions over this question were indeed divided in our technology assessment. In any case, if the burden of proof is to be reversed some additional rule would be needed to justify giving the benefit of doubt to the older technology. Without such a rule of preference, any technology, old or new, would fall victim to the suspicion of hidden risks.

The main weakness of regulatory schemes which reverse the burden of proof to minimise technological risk, is that they are unable to distinguish between acceptable and unacceptable innovations. The unsubstantiated assumption that a technology could involve unknown risks can always be made and can hardly be refuted. Empirical proof of a negative fact, in this case, that hidden risks do not exist, is a logical impossibility. One cannot, in a finite period of time, examine an infinite set of possible facts in order to demonstrate that it does not contain some specific element. Consequently, a strict reversal of the burden of proof would exclude all innovation. From the perspective of risk prevention, then, no new technology would ever be acceptable.

It seems plausible, therefore, to assume that those who insist on the strict reversal of the burden of proof have a moratorium on the freedom to innovate in mind. They want to replace control of risk as the test for approval of new technology with other criteria such as socioeconomic need or democratic vote. On the other hand, if it is accepted that new technology should be regulated within a framework of risk control, the burden of proof can only be reversed to a limited extent. One must be satisfied with indicators for relative safety and leave aside risk scenarios which can neither be tested nor substantiated. Then, only doubts justified by good reason will count as an argument *contra projectum*, and reversal of the burden of proof comes close to what we have in existing regulations under the precautionary principle.

9 Reversibility as a criterion?

Various efforts have been made to find criteria which take unknown risks into account without the need to ban new technologies outright. In the public debate, it was proposed that new technology only be permitted if its possible consequences are reversible. In the event of unexpected risks, it must be possible to revoke the approval of a technology without leaving lasting damage. This criterion was adopted by some participants in the technology assessment, who argued that genetically engineered organisms—in contrast, for example, to chemicals—were able to reproduce themselves and multiply, and hence could not be recalled once they have been released in large quantities. These participants felt that transgenic herbicide-resistant crops should be banned, as a precautionary measure to ensure that no irreversible harmful effects on nature could occur.

Reversibility or retrievability seem plausible criteria. Responsible decision making ought to consider whether and at what cost it would be possible to reverse a decision, should it turn out to have been a mistake. However, the question again is whether this is a viable criterion for precautionary regulation of transgenic plants. We may disregard the philosophical objection that, strictly speaking, no decision is reversible since historical development and natural evolution continue, and the world can never be the same as before. From a practical point of view it is sufficient to distinguish between consequences which are more or less irreversible, and in this sense pharmaceutical products can be recalled, whereas released organisms and their genes are not. The main objection in the technology assessment was that no difference can be made as far as reversibility is concerned between transgenic and nontransgenic crop plants. As a rule, the crops developed using conventional breeding techniques are also able to reproduce; they are just as difficult (or easy) to retrieve as genetically engineered crops and they can, under certain circumstances, induce irreversible changes in the ecosystem and natural evolution.

If reversibility were really taken seriously as a condition for approval, then conventionally bred crops would also not be allowed. This would clearly be absurd. There is general consensus that such crops be accepted. Lack of reversibility cannot be a sufficient reason to ban any new crop. In the final analysis regulation returns to the issues of risk. The relevant question is whether a crop will have harmful consequences, not whether the consequences will be reversible. Accordingly, possible damage from transgenic herbicide-resistant plants was the central topic in our technology assessment, not whether the release of such plants can be reversed or not.

10 Regulatory responses to anxiety

The assumption that transgenic plants pose new, unknown risks which, in extreme cases, could prove fatal or catastrophic may be arbitrary and scientifically unfounded and therefore unsuitable as the basis for regulation. However, fear of unforeseen consequences is psychologically plausible and probably widespread. People need not have particularly good reasons to be seriously worried; it may be sufficient that genetically engineered plants are novel and unfamiliar. Anxieties are a legitimate political signal, even if they cannot be justified on scientific grounds. In a democracy, citizens' feelings count; everyone has, so to speak, the right to choose what he or she fears and what not. On the other hand, this does not imply a right to have one's fears put at the basis of collective regulation. Under the German constitution it is not possible to ban a technology merely because some people are afraid of it. However, there is no reason why the law should not respond to the anxieties of the people by imposing additional safety measures short of a complete ban on the technology.

Some recommendations along these lines were made in the normative discussions in our technology assessment. It was proposed that additional tests and monitoring be required for transgenic herbicide-resistant crops.[92] These

[92] See section III E below.

requirements should apply even if there were no reasons to suppose that these plants are in any way more dangerous than plants developed using conventional breeding. This asymmetric treatment of transgenic plants could be regarded as a sort of safety penalty for the novelty of the technology.

Regulations which are not based on identifiable risks but on the novelty of genetic engineering are increasingly denounced as anti-modernism in the international discussion. Such regulations were, however, not really in dispute in our technology assessment. They represent a kind of tribute to the lack of acceptance of genetic engineering among the general public (albeit an insufficient tribute according to the critics). Transgenic plants are frequently viewed with suspicion, whereas new conventional plants are widely accepted without reservation. This divergence of opinion will probably not be overcome in the short term by reiterating that the identifiable risks for both types of plants are equivalent. Additional safety measures seem to be an appropriate response. They can be imposed for a limited period of time. They are open to revision and they do not represent an unreasonable restriction as long as they do not in fact amount to an attempt to obstruct the introduction of transgenic plants altogether.

C NONSELECTIVE HERBICIDES: ARE THE BENEFITS APPRECIABLE?

Public debate is preoccupied with the control of risks involved in genetic engineering. However, this is only one of the issues generated by transgenic herbicide-resistant crop plants. Another issue is the use of nonselective herbicides in agriculture, which becomes a feasible option for weed control if herbicide resistance genes are engineered to crop plants. The risks and benefits of such a strategy have been dealt with in numerous reports and discussions in the technology assessment. The results are, to put it cautiously, nonspectacular. As was shown in sections II B and II C above, neither grave risks nor dramatic benefits can be expected:

- Nonselective herbicides will not pose any particular problem of residues in food products. The situation is basically the same as it is with the introduction of new selective herbicides.
- The overall amount of herbicides used in agriculture is likely to decrease; in some crops considerable savings could be achieved. There could be some increase, however, in marginal areas if mechanical methods of weed control are displaced.
- Nonselective herbicides such as glyphosate or glufosinate are slightly better in terms of environmental impact than the herbicides they would replace. Rapid degradation in the soil and reductions in the amount of herbicides used will theoretically reduce the risk of groundwater contamination. Measurable effects on levels of erosion are not to be expected. The use of only one nonselective herbicide with monocultures or in the all crops of a rotational sequence could result in the loss of rare weed species from the seed bank.
- Nonselective herbicides improve agronomic conditions by providing new options for flexible postemergence application and better control of problem weeds. Nonrotational use of such herbicides could, however, increase the selection of herbicide-resistant weeds. New opportunities for systems of integrated crop management (e.g. direct drilling, ground cover crops) may remain purely theoretical, since they may not be economic under present conditions.
- For some crops, nonselective herbicides will offer financial benefits for farmers because weed control becomes cheaper.

These findings were considered provisionary, since they were based on assumptions about the use and effects of nonselective herbicides, which may have to be modified when more data are available from field trials and practical experience. But they were not really in dispute among the participants in our technology assessment. The dispute was over the normative evaluation. Many participants rejected the conclusion while that nonselective herbicides promise only slight advantage, they at any rate have no significant disadvantage and their use, therefore, constitutes an acceptable method of agricultural management. Participants disagreed over the assessment of existing regulations, over the proper criteria of benefit, and over fundamental issues of future development in modern agriculture and the role of technological innovation in our society.

1 Regulations as a factor in risk-benefit analysis

It was a common practice throughout the technology assessment to counter arguments about possible risks, disadvantages and misuses of nonselective herbicides by saying*: ”the argument is true, in principle, but irrelevant, in practice, because existing regulation is coping with the problem”.* This form of counter-argument considered ”unfair” by some participants. Indeed, one can easily make the results of any risk-benefit analysis positive, by assuming ideal regulations and controls which will eliminate all negative factors. At the other extreme, however, it would also be misleading if regulations were not considered at all. No technology in our society is approved without any restriction. Therefore, a risk-benefit analysis of transgenic herbicide-resistant plants can take into account legitimately the established regulatory framework (testing requirements, rules of application, liability etc.), to determine what the impacts of such plants would be. Nor would it be "unfair" to recommend new regulations and to argue that these would solve the problem and make the technology acceptable. To the contrary, such recommendation is clear evidence that risk-benefit analysis will yield different results with or without the proposed regulation. For example, if nonselective herbicides were continuously applied without rotation, they would cause the total eradication of some weed species from the seed bank, and this must be counted as negative according to standards of "integrated crop protection". However, if proper regulations ensure that these herbicides are used only once with rotational crops, their impacts will probably be neutral or, in some respects, even positive.[93]

A risk-benefit analysis may have to disregard problems which are dealt with by proper regulation. But it is still a legitimate argument that existing or proposed regulation is in fact not adequate to solve the problem, or that the rules would not be observed in practice. Arguments on this line were raised against all regulation concerning herbicides by the critics in our technology assessment. In particular they referred to the limits of preventive testing, both in terms of size and validity of tests (use of animals and model systems). Critics also claimed that compliance with existing rules would be particularly low in the case of nonselective herbicides.

All participants in the technology assessment admitted that the tests for herbicide approval have limitations, but many contested the claim that, because of these limitations, existing regulations could not guarantee the safety of health and environment. They pointed out instead that the regulations had apparently been sufficient in the past to prevent damage. If unexpected harmful effects from herbicides occurred, the regulations could be tightened or approvals for the herbicides withdrawn, as in the case of the ban on atrazine and paraquat in Germany (because of groundwater contamination or lasting soil impacts). Since our technology assessment was not supposed to judge herbicides in general, the debate on the scope and predictive power of preventive testing for approval of herbicides remained a side issue in the discussions. There was agreement that the development of better test methods and models in toxicology and ecology is desirable. However, the argument that available tests should be dismissed as useless because they have inherent limitations was clearly rejected: that would eliminate all objective, reproducible criteria from predictive risk assessment.

One thing the debate did achieve was to call to mind that regulations should not make unrealistic guarantees of safety. No preventive testing can exclude every risk; it can only control a finite set of clearly defined risk assumptions. There can always be risks which will not be controlled, because they are unknown or untestable. Thus, if tests find no risk, this is strictly speaking, only an indication of relative safety, and not a proof of full safety. The fact that we accept such indicators and consider a technology safe (enough) once it has passed the tests for approval, is a political compromise between minimising risks and enabling technological innovation.

Since it is impossible to test for all conceivable negative effects, any regulation of new technology must draw a distinction between possible effects which can be tested and controlled before the technology is approved, and possible effects which must be tolerated without being tested. This applies as well to the approval of nonselective herbicides and of transgenic herbicide-resistant cultivars. Uncertainties which may still be implied by such cultivars but have not been controlled by preventive tests will, in legal terms, count as residual risk which may be imposed legitimately on the society. In political terms, however, the question of what constitutes an acceptable residual risk when herbicides are approved is a highly controversial matter—both in the public debate, in general, and in our technology assessment. While it is true that tests which prove, to the negative, that no risks exist, are impossible, it is always possible to test more than has been done up to now. Therefore, there will always be room for new demands to tighten the conditions for herbicide approval.

This dispute is not likely to be resolved because of the underlying disagreement over whether herbicides should be approved at all, in the first place. Those who reject all use of herbicides will demand ever more exacting tests, even if this makes the introduction of new herbicides virtually impossible or uneconomical. Those who consider the use of herbicides acceptable and necessary in agriculture will advocate limited

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93 See above section II C2.

testing programmes and warn against ”over-regulation”. It would be honest, in this dispute, to do away with the misleading scientific rhetoric that preventive testing will prove the safety of a new technology; instead one should admit that some compromise between what is tested, and what is not, is always implied. Political and moral arguments must then explain why this compromise should be accepted as fair and fitting. On the other hand, it is dishonest to drive demands for stricter regulation to the extreme: those who press for ever more preventive testing as a means to exclude all conceivable risk, should admit instead that they really seek the total rejection of the technology, regardless of testing.

2 Shifting criteria of evaluation

Any risk-benefit analysis requires evaluation criteria. What counts as damage, what as benefit? In many cases the answers are clear. In general, there is a social consensus on basic goals and values (human rights, protection of the environment, productivity in agriculture). Pluralism does not mean that people live in separate normative worlds. Disagreement arises over questions of how accepted goals and values should be realised in concrete situations, and how priorities should be set if they are in conflict. When it comes to these issues, pluralistic moral attitudes and political preferences will prevail. This was especially the case in our technology assessment whenever the development of acceptable or desirable forms of agriculture was at issue. The debate over whether protecting the diversity of weed species is a proper goal when we consider agricultural farmland, can serve as an example.

We can assume that the widespread use of nonselective herbicides will reduce weed seed banks and occasionally eliminate rare weed species from the areas treated. Is this a negative factor in the risk-benefit analysis? If we apply the criterion of nature conservation, then the loss of a rare species in a region constitutes significant damage; this criterion demands that the existing spectrum of species be preserved over the widest possible range of sites. But is this a proper criterion for evaluating a method of weed control? Evidently, where farmland is concerned, some aspects of biodiversity will give way to aspects of productivity. Agriculture gives, by definition, preferential treatment to crops over other plant species. All forms of agriculture, including organic farming, attempt to eliminate most weeds from the fields and reduce the pressure from weed seed banks. Weed control entails some loss of biodiversity. In addition, local or regional biodiversity within agricultural habitats is in any case contingent upon the choice of crops to be cultivated. If certain crops are no longer cultivated (for instance, sugar beet in Central Europe if alternatives become available), then the weed complexes associated with these crops will disappear from the fields. The same applies if large areas are set aside or reforested. Therefore, in contrast to natural ecosystems, it makes no sense to regulate agricultural habitats with a view to preserving existing biodiversity. If necessary, reserves would have to be created for rare weeds outside agricultural areas.

Some participants concluded from this that species conservation should have no significant role in the assessment of nonselective herbicides. The general feeling was, however, that while production must have priority on farmland, this does not imply a *carte blanche* for unrestricted eradication of weed species. This is in line with the German *Plant Protection Act* which rules that herbicides cannot be approved if they impair the ”household of nature”. However, there was no agreement concerning to what extent species conservation on farmland is compatible with agricultural production. Those who considered organic farming as a feasible and desirable alternative to conventional, intensive agriculture felt that any loss of weed biodiversity from herbicide use was avoidable and should therefore count as damage. Consequently, these persons were not impressed by the argument that nonselective herbicides would not reduce weed stocks more than would the tank mixtures of selective herbicides used at present; they demanded instead that weed control be carried out in general at much lower levels. A common ground for evaluation accepted by all participants was the notion of ”integrated crop protection”, with the objective to reduce the chemical load on agricultural fields, if possible. The majority accordingly rejected permanent, nonrotational applications of nonselective herbicides because this is likely to lead to extreme depletion of weed seed banks.

3 Are small benefits appreciable?

Most of the participants in the technology assessment felt that transgenic herbicide-resistant crops did not represent a major technological breakthrough in chemical weed control. These crops contribute to innovations that were already in place before, like shifting to postemergence treatment using split doses of herbicides. Technically speaking, nonselective herbicides are equivalent to new postemergence, selective herbicides. They will offer some advantages with respect to flexibility and cost of weed control, and with respect to more effective elimination of problem weeds (especially in row crops). However, most participants saw little reason to vest great hopes of agronomic benefits in them.[94]

This assessment raised some basic questions of evaluation to be dealt with in any risk-benefit analysis: Are small benefits appreciable? Is a technology acceptable if it improves the status quo moderately, or must the status quo be evaluated as well? Will any improvement to the status quo suffice to ”really” solve the problems? Should alternatives to the technology be assessed in comparison?

There was broad agreement that risk-benefit analysis implies a limited frame of reference. It makes little sense to extend the evaluation to technology in general, if we are to assess transgenic herbicide-resistant crops. There will always be some innovations which are more worthwhile to pursue. And there will always be other problems against which the possible harmful effects from herbicide-resistant crops appear to be negligible. Therefore, opportunity costs (i.e. how the resources necessary for the development, introduction and regulation of herbicide-resistant crops could be put to better use) should not be considered. Conversely, the fact that destruction of tropical rain forests is the primary cause of loss of genetic diversity cannot be used as an argument to ignore the negative impacts herbicide-resistant crops might contribute to that problem.

Even so, the choice of reference level remained a problem in the technology assessment. For example, participants agreed that herbicide leaching into groundwater must be prevented and that savings in the amounts of herbicides used in agriculture are desirable. But views as differed over whether a reduction of 10 to 20%, expected with nonselective herbicides, constituted any real improvement. Some took current levels of groundwater pollution as the point of reference, others the optimum of zero pollution required by the precautionary principle. The latter would only accept reductions in herbicide use of at least one order of magnitude (i.e. to one-tenth or one-hundredth) as a real improvement.[95] In the discussions on soil erosion it was argued that any improvements that might result from a shift to postemergence, nonselective herbicides should be ignored because, on the one hand, they were in no way adequate to compensate for existing losses from erosion and, on the other hand, they would be superfluous if proper site-specific crop management were observed.

A reduction in the amount of herbicides used was generally booked as an ecological benefit. However, participants in the technology assessment, who rejected herbicides in principle, did not find them more acceptable or ecologically beneficial just because they would be used in smaller quantities. With respect to the economic evaluation, some participants criticised that reduced cost of agricultural inputs and products was taken as the criterion of benefit, because this implicitly accepts the status quo, namely, the practices of intensive farming, as the starting point. They argued that if external costs were included in the economic assessment—especially negative environmental effects and also social problems—then conventional, intensive farming as a whole might prove ”uneconomical”. In this case, relative improvements in terms of reduced costs for the farmer could no longer be considered an economic benefit of herbicide-resistant crops.

This pattern of argument repeated itself throughout the discussions in our technology assessment. While some individuals emphasised that relative ecological or technological improvements were to be expected, others argued that such ”improvements” should not count because, in absolute terms, they merely amend a state of affairs which was not acceptable from the outset. They make things ”less bad”, at the most, but not ”good”, and they do not, therefore, represent any real benefit.

How the frame of reference for evaluation is selected, is itself a matter of evaluation. The choice cannot, in the final analysis, be refuted but merely laid open. It then becomes apparent that such choices need not be consistent. People found it convenient to shift the frame of reference to suit their interests in the argument. For example, in our technology assessment, changes in the amounts of herbicides used were valued asymmetrically by many participants: a 10% reduction was not considered an improvement at all, but a 10% increase would clearly have been rated as a change for the worse. In the latter

[94] This rather tentative assessment may have to be modified in view of the results from recent field trials; see above section II B2.

[95] Expert report of G. Klein: ”Auswirkungen der HR-Technik auf aquatische Ökosysteme”, in: *Materialien zur Technikfolgenabschätzung, Heft 9* (see appendix).

case, the status quo of herbicide inputs is the starting point of reference for evaluation; in the former case, it is not. Similarly, a slight reduction in water pollution, which might result if nonselective herbicides are applied in lesser amounts, was not considered a real benefit; but an equally small increase which might result if more herbicides were washed off leaves was considered to represent real harm.

Nevertheless, there is still scope for a balanced political assessment of herbicide-resistant crops, irrespective of the frame of reference adopted for evaluation. Even if one concedes that any improvements achieved through such crops were only variations of a status quo which itself must be regarded as problematic, one could still argue that we ought to do what we can to improve this status quo step by step. The counter-argument is that this is treating the symptoms but not curing the disease. Although this may be true, it is still not a sufficient reason to reject herbicide-resistant crops altogether. Why should a positive development be rejected just because it does not go far enough and cannot solve all the problems at once? It is possible to justify herbicide-resistant crops as an option that offers moderate agronomic and environmental benefit and, at the same time, emphasise that these crops represent no significant contribution to the more ambitious goal of making modern systems of agriculture sustainable. This argument will, however, not be acceptable to those who oppose the use of herbicides as a matter of principle.

4 Reference to intensive agriculture or to organic farming?

Normative discussions in the technology assessment frequently ended up with more fundamental questions of how agriculture should be developed in the future. If the prevalent system of intensive agriculture is considered to be neither worthy nor capable of being reformed, then virtually no improvements to this system would count as real benefits. Accordingly, it was argued by some that the technology assessment dealt with the wrong issues. Instead of assessing only transgenic herbicide-resistant crops, a comparative assessment of alternative systems of agriculture (intensive versus organic farming) would be needed.

Our technology assessment indeed only posed limited questions and can therefore only give limited answers. In deriving conclusions with respect to possible ecological, agronomic and economic benefits of herbicide-resistant crops, conventional, intensive agriculture was taken as the frame of reference. The question was whether or not we can expect relative improvements compared with current weed control practices. The context of these practices—cultivation of high-yield crops, small crop rotations, and high chemical inputs of fertilisers and pesticides—were taken as given.

Our technology assessment was not supposed to engage in a systematic, comparative evaluation of alternative farming systems. However, participating environmental groups operated on the premise that were such a comparison to be made, organic farming would come out ahead, and that it could (and should) replace conventional farming on a broad scale. This view was contradicted by others whose main argument was that organic farming could not ensure food supply for the world population. Nor was it accepted unconditionally that organic farming represents the superior model in terms of environmental impacts and sustainability.

Whereas no participant would probably have denied that organic farming has a better environmental record than conventional agriculture, many insisted that conventional agriculture could prove an equally viable alternative in environmental terms if it were developed according to the principles of ”integrated crop management”. Opinions were divided over this question. However, even the advocates of organic farming did not rule out that, with appropriate management, conventional agriculture could be continued indefinitely and also fulfil the criterion of sustainability. They did not claim that present agriculture would inevitably lead to the ecological collapse of food production and that, for this reason alone, the transition to organic farming was indispensable. The question whether organic farming could completely replace conventional agriculture as the basis of world food production was not extensively discussed. This issue is mainly of ”academic” interest since even the advocates of organic farming did not assume that the phasing out of conventional agriculture was a realistic political goal for the near future. It is obvious that any transformation to organic farming would not imply an abrupt switch from one system to the other; but at best it would mean a slow, progressive shift in emphasis between two co-existing strategies.

The dispute over which form of agriculture we should develop was in many ways the real core of political disagreement over transgenic herbicide-resistant crops. Nevertheless it would not be appropriate to evaluate these crops solely within the broader framework of alternative systems. Even advocates of organic farming would have to admit that improvements in conventional agriculture could be highly relevant, since this form of agriculture is what is practised on almost the total area of farmland in the industrialised countries and much of the Third World, feeding billions of people. Thanks to increased yields in conventional agriculture (including the so-called Green Revolution), food production has been able to keep up with population growth in recent decades. At least for the time being, therefore, hunger is more a problem of distribution than of production. A realistic, short-term alternative to replace the present system is not in sight. Despite all their differences, participants in our technology assessment would not have disputed that organic farming methods could not take over the role of ensuring food supply on a global scale in the foreseeable future; nor perhaps would it ever be able do so, on the basis of its present level of productivity. One must therefore concede that—dramatic political and technological revolutions notwithstanding—a growing world population will continue to depend on conventional agriculture, and steady agronomic, ecological and economic improvements in this type of agriculture are absolutely indispensable.

D USEFULNESS AND SOCIOECONOMIC NEED AS CRITERIA FOR APPROVAL: A ”FOURTH HURDLE” FOR INNOVATION?

What benefits might be obtained from transgenic herbicide-resistant crops is, without a doubt, a central topic in a technology assessment. But how relevant is it for decisions about the technology? Seed producers and chemical companies will try to estimate the economic advantages before they invest in transgenic herbicide-resistant crops, and public funding should be withheld if these crops do not promise a benefit for the community.[96] But to what extent should a legal test for benefits become a criterion for the approval of new technology? Could/should transgenic herbicide-resistant crops be banned because they offer no real benefits or because we actually do not need them as equally good or better alternatives are available?

These questions were the subject of controversy in our technology assessment. Discussions centred in part on the limited risk-benefit analysis required by the German law (article 16 of *the Genetic Engineering Act*, article 15 of the *Crop Protection Act*). In part, they were concerned with more radical demands to extend the political control of innovation in our society.

1 Risk-benefit analysis under the German Genetic Engineering Act

According to article 16 of the *Genetic Engineering Act*, transgenic herbicide-resistant crops may only be released or placed on the market if

> ”according to the available scientific evidence no effects are to be expected which are unjustifiably harmful in view of the purpose of the release”.[97]

The elements to be considered for such a decision were brought together in our technology assessment. Most participants assumed that transgenic herbicide-resistant crops would pass this test and could be approved.[98] However, several aspects need to be clarified: When is a risk-benefit analysis necessary (admissible)? What effects have to be taken into account in assessing damage?

One question is whether a release can at all be justified by weighing the risks against the purpose, if harmful effects are not only a possibility but definitely to be expected. Can benefits only compensate for risks, that is, for harm that would result from transgenic organisms if some unfortunate circumstances occur? Or can benefits also compensate for imminent danger, that is, for damage inherent in the application of such organisms? The European law seems to rule that, in the latter case, approval must always be denied without any consideration of benefits.

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[96] Probably because of public criticism surrounding the project, the German Ministry for Research and Technology decided not to become involved in the funding of the development of transgenic herbicide-resistant crops.

[97] Harm is defined in terms of impacts on life and health of humans, on animals and plants, as well as other aspects of the environment and its fabric of interaction, and on material goods. See article 1.

98 In Germany, releases of glufosinate-resistant oilseed rape and maize were approved (for field trials only) in 1994. On the European level, herbicide-resistant oilseed rape and chicory were authorised for being placed on the market as seeds for breeding purposes (but not for food or feed) in 1996 (Official Journal, 1996 L, Nos. 37/30 and 175/25). Monsanto’s glyphosate-resistant soybean was authorised for food purposes in April 1996 (*Official Journal* L 107/10). Transgenic pest-resistant maize with a herbicide resistance gene as a marker was finally approved on the European level without restrictions for marketing in December 1996. France refused, however, to register the variety, which is a precondition for growing it (see *Nature Biotechnology*, 15, 1997: 308). Thus, the maize is not yet grown in Europe; import has been approved in all EC countries except Austria and Luxembourg (May 1997).

Directive 90/220 on the deliberate release requires measures "to avoid adverse effects" on human health and the environment (article 4). This question is controversial,[99] but it appears to have no particular significance for transgenic herbicide-resistant crops since these pose no specific risks for human health or the environment. The risks discussed in our technology assessment all referred to possible harm that was more or less remote and the probability of which could be further reduced by appropriate safety measures. Harm may nevertheless be possible, but that possibility can be compensated legitimately by the purpose (the benefits) of the technology.

On the other hand, weighing the risks and the purpose of a release is only necessary (and hence only admissible) according to the German law if adverse effects are to be expected with some degree of probability. Therefore, consequences which are possible or probable but not harmful need not be justified by the purpose of the technology. This would probably apply, for example, to horizontal gene transfer from crop plants to soil bacteria. Should herbicide resistance genes be transferred, the effect to be expected would be a temporary increase in numbers of transformed herbicide-resistant bacteria near the soil surface while the herbicide is active. Whether this in itself represents a harmful effect is questionable. For similar reasons the possibility that transgenes for herbicide resistance are outcrossed from crops to related wild species will be irrelevant. Since herbicide resistance does not represent any selective advantage in natural habitats, one cannot envisage ecological damage from occasional wild plants which might have taken up the transgene. Nor can the disadvantages resulting from the selection of herbicide-resistant weeds in agricultural fields be brought forward as damage in a risk-benefit-analysis. They constitute real harm to the economic interests of farmers or the chemical industry, but the protection of these interests is not covered by the *Genetic Engineering Act*. The same applies for negative consequences attributable not to the transgenic herbicide-resistant crops themselves, but to the use of the nonselective herbicides introduced with these crops. An example would be environmental damage that might result if nonselective herbicides were used particularly recklessly. Such problems concern the use of herbicides and are a matter for the plant protection law rather than the law for genetically modified organisms.[100]

It is generally agreed that so-called residual risks, that is, uncertainties about hidden risks, do not have to be compensated in a risk-purpose assessment under the German law. Consequently, harmful effects which cannot be predicted or described because they are not known are not taken into account, even if they remain a theoretical possibility. Many of the assumed risks which were the subject of controversy in our technology assessment fall under this category, for example, the assumption that herbicide-resistance genes which had been outcrossed to wild plants or transferred to soil bacteria could have unforeseen environmental or other novel effects not previously observed, or that they could initiate evolutionary developments which could prove harmful after many years. It is questionable whether any of the scenarios discussed in our technology assessment substantiated sufficient risk to warrant an assessment of purpose as a condition for the approval of transgenic herbicide-resistant crops under arti-

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[99] Expert report commissioned from Prof. E. Rehbinder (Fakultät für Rechtswissenschaft, Universität Frankfurt am Main): "Rechtsprobleme gentechnisch veränderter herbizidresistenter Pflanzen"; commentary by Dr. J. Steinberger (Bundessortenamt Hannover), in: *Materialien zur Technikfolgenabschätzung, Heft 18* (see appendix). Were the EC Directive to be applied strictly, then the need for revision would arise as soon as it would be necessary to consider a really useful application with unavoidable harmful effects. It would hardly be appropriate if it were not even possible to consider whether, for example, the use of genetically modified microorganisms against the malaria mosquito might not warrant certain levels of water pollution or a shift in the species spectrum of the food chain. See the official commentary on article 16 in Hirsch and Schmidt-Didczuhn (1991, No. 17).

[100] This is also the standard rule in the European law. The impact of transgenic herbicide-resistant crops on the practice of herbicide use in agriculture is outside the scope of Directive 90/220; see, for example the decision by the Commission on herbicide-resistant chicory (*Official Journal*, 1996 L, No. 175/25). Such arguments may nevertheless be used to block decisions in the respective committees (see IHE, 1996: 5). The legal separation of safety issues from socioethical problems runs counter to the mood of public debates and policy advisory bodies which represent a broad range of interests. The excluded aspects must either be dealt with in other legal arenas or be taken up in informal deliberations and dialogues "surrounding" decision making on genetic engineering; see, for the Netherlands, Schomberg (1996). However, a number of countries (Denmark, Austria) explicitly refer to social criteria in their gene technology laws; see Levidow *et al*. (1996: 148) and below. On the other hand, any risk-benefit-analysis under the *Genetic Engineering Act* would have to include agricultural disadvantages and problems related to the use of nonselective herbicides as negative factors in assessing the benefits of herbicide-resistant crops; these factors reduce the benefits to be taken into account. But benefits would only be assessed after it has been decided that harmful effects must be expected.

cle 16 of the German *Genetic Engineering Act*. Perhaps one could argue that the risk of unexpected metabolic side-effects in food crops is an example. This risk must be tested in every case, but it still cannot be completely ruled out. If it is not classified as a residual risk, it would have to be balanced by the purpose (the benefits) of the release. Moreover, the definition of what constitutes harm is not a mathematical exercise. And with no established jurisdiction in this field, it is difficult to predict whether the judgement that horizontal transfer or outcrossing of herbicide resistance genes does not constitute harm, will finally be accepted by the courts. It seems advisable, therefore, to consider what benefits could be pointed out to compensate for such risks.

Insofar as only field trials are concerned, the benefits to be considered are increases in knowledge about the performance and the effects of transgenic herbicide-resistant crops under field conditions. When transgenic crops are placed on the market, the benefits to be considered will include reductions in the amounts of herbicides used, better control of problem weeds, greater flexibility and higher crop yields. Small improvements relative to the status quo must be taken into account (with appropriate weighting). There seems to be no legal basis for the demand raised by some participants in our technology assessment that a reduction in herbicide use amount to at least one order of magnitude (one tenth) less before it could really count as a benefit. Any reduction in the use of chemicals for crop protection is a legal objective according to the German *Plant Protection Act* (article 6).[101]

In balancing the risks and purpose of transgenic herbicide-resistant crops it seems legitimate to consider as well that the risks to be compensated (like uncontrolled metabolic changes or increases in fitness) also exist for conventionally bred plants. It is true that comparability of risks does not imply acceptability. The very fact that special legislation has been enacted for genetically modified organisms suggests that transgenic crops could be subjected to stricter controls than conventionally bred plants. The German law requires safety measures corresponding to the state of scientific knowledge (*Stand der Wissenschaft*), which generally means a particularly high standard of precaution. However, if, despite the safety measures transgenic crops still involve risks, and if these risks are comparable to those normally accepted with conventionally bred plants, then a moderate benefit should suffice to outweigh them in the risk-purpose assessment. It can be assumed that transgenic herbicide-resistant crops would meet this requirement.[102]

2 Have alternatives to genetically engineered crops to be taken into account?

Whenever risks and benefits have to be balanced the question of alternatives comes to the fore. Can the benefits of transgenic herbicide-resistant crops justify the risks when other options are available for weed control, with the same or lower risks? Can approval be denied if these crops, although useful when viewed in isolation, are not better than what we already have? There is no provision in article 16 of the German *Genetic Engineering Act* that alternatives have to be taken into account. This may nevertheless be required under the general principles developed by the German Federal Administrative Court in the paraquat case.[103] However, the law poses tight restrictions here.

It is uncontested that the risk-benefit assessment under article 16 may not be used to test for socioeconomic need nor to enforce political

[101] On the other hand, it is questionable whether it can be considered a benefit that, with transgenic herbicide-resistant crops, farmers have better options for the management of monocultures (as concluded by Rehbinder in his report, p. 27). Such options are hardly compatible with the rules of "integrated crop protection". In our technology assessment, they were considered as a disadvantage and as abuse of herbicide-resistant crops, even if farmers could benefit economically in the short term. Like other agronomic disadvantages, they do not add to the risks of transgenic crops; rather, they reduce the benefits which can be taken into account.

[102] This conclusion is based on two assumptions: (1) Certain harmful effects are possible if we release transgenic herbicide-resistant crops. (2) The possibility of such effects will be outweighed legally by the benefits of these crops. This interpretation would not be valid if the law really required that "harmful effects on the environment must be excluded" (see Rehbinder, p. 25). Strictly speaking, this formula would bar any approval of transgenic herbicide-resistant crops, irrespective of purpose or benefit. According to the results of our technology assessment, harmful effects cannot be excluded. This does not just mean that it is logically impossible to exclude unknown risks: it is also not possible to reduce realistic, identifiable risks to zero. It is only possible to show that the risks are very small or that they can be made very small by appropriate precautions. If there is an application for the risk-purpose assessment of article 16, it should lie here.

[103] Judgement by the German Federal Administrative Court, 10 November 1988, Volume 81, p. 12: Approval of a herbicide which has considerable effects on the household of nature may be denied, because substitutes are available that have fewer effects and that are suitable for the farmer in agronomic and economic terms. See also Rehbinder, p. 40.

choices of the technology on which agriculture should be based. Competent authorities have to examine whether transgenic herbicide-resistant crops are useful, but not whether they are actually needed. And it is not an admissible legal argument that herbicides and thus herbicide-resistant crops can be spared altogether if agriculture were shifted to organic farming. Alternatives that might have to be taken into account are technical options for weed control without transgenic herbicide-resistant plants. Mechanical methods will not usually be considered because they have agronomic and economic disadvantages and are not an equivalent option.[104] But selective herbicides with comparable performance and equal or less risks than nonselective herbicides would provide a suitable alternative. Such alternatives might in fact be available, at least for some crops. Has this any legal implications for the risk-benefit balance of transgenic herbicide-resistant crops? Two arguments could be made in this respect. The first is that, because alternatives are available, no benefit accrues from herbicide-resistant crops. The second is that, because alternatives are available, the risks posed by herbicide-resistant crops are unacceptable. Both arguments are to the same point but with a slightly different focus.

When we compare benefits of different technologies, we may find that one is more useful than the other. However, we would not normally conclude from this that only the best one is really useful and that the others offer no benefit at all. The very fact that we do have different versions of a technology, in our case, that we have more options for herbicide use, can itself represent a benefit. In general, the approval of a new technology is not contingent upon its representing real progress compared to an older technology.[105] Older herbicides do not lose their authorisation when new and better products are brought onto the market, and new herbicides can be launched even if existing ones are as good or better. Consequently, it would not be legitimate to reduce the benefits of transgenic herbicide-resistant crops to zero just because nonselective herbicides may not be better than already existing selective herbicides.

In evaluating risks, alternatives may have greater significance since, according to the paraquat ruling, environmental impacts of herbicides may be unjustifiable if suitable alternatives are available. This ruling presupposes that the impacts exceed the levels normally to be expected from herbicide use. In line with this reasoning, one could perhaps argue that risks involved in transgenic herbicide-resistant crops are unjustifiable (and cannot be compensated by benefits) (1) if they pose an imminent danger to protected legal goods and (2) if selective herbicides are available from which harmful effects are less probable. Our technology assessment suggests that the possible risks from transgenic herbicide-resistant crops do not meet condition°*1*. They refer to possibilities of damage, which are either remote or ”normal” in dealing with crop plants. Therefore, it should be legitimate to compensate them with possible benefits. There is no established rule under the precautionary principle that alternatives must be taken into account in order to minimise risks, and that when alternatives are available, only the technology that implies the least risk can be approved. Such a rule does not even apply for nuclear energy. If it were adopted then, in the case of transgenic herbicide-resistant crops, the alternatives to be taken into account would be conventionally bred plants (and not selective herbicides). However, on the basis our technology assessment, it is questionable whether less harmful effects are to be expected from conventionally bred plants than from transgenic ones.[106]

In conclusion, any suggestion that transgenic herbicide-resistant crops should only be approved if they offer clear advantages over previously applied strategies of weed control would be treading new legal ground. It advocates the

[104] Following the ”paraquat” ruling they would nevertheless have to be considered if severe impacts on the household of nature were to be expected from nonselective herbicides, which exceed those levels usually caused by herbicides. Having to tolerate such impacts would be unjustifiable, if mechanical methods were an available and suitable alternative. However, no evidence was produced in our technology assessment that severe impacts must indeed be expected. Therefore, as long as the availability of mechanical methods of weed control is not a sufficient reason for denying the approval of herbicides in general, it will also not be possible to use it as a legal argument against the approval of transgenic herbicide-resistant plants.

[105] The certification of new plant varieties is an exception to a certain degree; new varieties only get listed if they pass the test of ”value for cultivation and use” which, according to the German law, requires that a ”noticeable improvement” compared to existing varieties is to be expected (article 34, *Saatgutverkehrsgesetz*); see also Rehbinder, p. 8.

[106] It would seem that there is also little scope for taking alternatives into account in herbicide approval. Nonselective herbicides tend to have less and not more impact on the household of nature than commonly used herbicides. The risk that rare weed species could be eliminated by excessive reductions in weed seed banks may require additional regulation; it hardly justifies denial of approval for nonselective herbicides because alternatives are available.

rule that old technology should be given precedence over new, and that "novelty" is sufficient reason for rejecting a technology if no additional benefit can be demonstrated. It was surely not the intention of the German law to subject genetically modified organisms to such a rule. That would have been expressed clearly in the *Genetic Engineering Act*. This rule cannot, therefore, be introduced through the back door of the risk-purpose assessment required under article 16 of the act.[107] However, participants in the technology assessment discussed whether such a rule was desirable, in principle, and whether it should be included in the law in the future.

3 Socioeconomic need as a criterion for technological innovation

In a way, the postulate that new technology should only be approved if it is shown to be socially useful and to fulfil a real need, was the logical endpoint of the risk debate in our technology assessment. It refers to residual (hidden) risks and implicitly admits that no conclusive argument could be formulated against transgenic herbicide-resistant crops within the common framework of risk regulation. The central argument is simple: If no innovation can escape the risk of harmful effects which we do not know and therefore cannot test in advance, then we should take this risk only if the innovation is really worth it. A technology which, strictly speaking, is superfluous because it serves no acceptable need or because appropriate alternatives are available, does not even justify residual risks being imposed on the society.

This is a standard argument of the critics of modern technology in many areas. It was brought before the European Parliament by a member of the Green Party, who advocated a "fourth hurdle" in the regulation of innovation. New technologies or products should not only pass tests of safety, efficacy and quality, but also the test of socioeconomic need.[108] It was rejected by mainstream policy and, as was to be expected, met with opposition in our technology assessment as well.[109] The objections were in part pragmatic and in part a matter of principle.

Pragmatic arguments considered problems of delimitation: *What counts as need?* Are transgenic herbicide-resistant crops only needed when existing herbicides have gaps in their weed control spectra which can only be plugged with nonselective herbicides? Or, is there also a need for additional herbicides even if they are not better than the existing ones? Is the farmer's interest in cutting costs an acceptable need? And what about lower food prices, or jobs created in the breeding sector? Obviously, the assessment of social need depends on which short and long-term effects of new technology are taken into consideration. One could solve this problem by taking only direct effects of the new technology or product into account. This is the practice under current law, in determining benefits which might balance risks. In this case, the assessment would have to be confined to the intended application of transgenic herbicide-resistant crops and consider the need for technically reliable, environmentally friendly and economically viable weed control. This proposal does not

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107 Nor can it be read from the European law.

108 Breyer (1992), as rapporteur of a draft report for the Committee on Energy, Research and Development. Hiltrud Breyer, member of the German Green Party, criticises the intention of the Commission of the European Communities (CEC 1991) to exclude socioeconomic and need criteria from the regulation of products of genetic engineering.

> "This position runs counter to that repeatedly taken by the European Parliament in its recommendations on genetically engineered Bovine Growth Hormone (BST) and to the views of numerous public interest organisations. Such a stance will make it difficult . . . for example, to make sure that a particular product will not exacerbate existing agricultural surpluses or result in further decline in small farming operations" (1992: 8).

109 The Commission of the European Communities intends to assess products only under the conventional criteria of safety, efficacy and quality. "By their nature, socio-economic aspects need to be considered in a different way. It is not the intention to have another systematic assessment in addition to the three criteria" (CEC 1991: conclusion); see also Cantley (1995: 639). The US Office of Science and Technology Policy has emphasised that regulation should be confined to risks. "The risk-based approach is scientifically sound, properly protects public health and the environment against risk, and avoids hindering safe innovations. . . . Determining the scope of oversight on grounds other than risk would also tend to discourage useful innovations" (OSTP 1992). The German government followed that reasoning when it proposed to amend the *Genetic Engineering Act* in 1993. "Restrictions of the use of genetic engineering are only warranted to the extent that they are justified to protect humans and the environment" (*Bundestagsdrucksache 12/5145: 10*). The Austrian *Gene Technology Act* of 1994 includes, however, broader criteria. The government has a mandate (and an obligation) to issue special regulation in order to prohibit products if they "could lead to a burden on society or social groups, which cannot be compensated and if the burden on the society appears unacceptable for economic, social or ethical reasons" (section 63). The Norwegian *Gene Technology Act* of 1993 requires "that in deciding whether or not to grant the application significant emphasis shall be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development" (section 10); see Backer (1995).

answer the question, however, how alternatives have to be taken into account in the assessment of social need. Is need to be denied if suitable selective herbicides or nonchemical methods of weed control are available? Is it a valid need argument that herbicide-resistant crops are superfluous because crop sequences could be changed or organic farming methods used?[110]

These questions indicate that more fundamental problems are involved in the proposal to introduce "need" as a legal prerequisite for innovation: *Who decides* whether there is a proper need for a new technology? Acceptable social demand is not an operational legal criterion. To determine such demand (particularly if available alternatives have to be weighed against one another) implies wide-ranging political choice and this is the prerogative of the legislator. Therefore, normal standards of the rule of law, which establish a separation of powers in all democratic societies, seem to exclude that decision making be relegated to regulatory agencies. A "fourth hurdle" which implies a mandate for regulatory agencies to determine whether the society really needs some new technology would be out of the question. In any case, it could not be upheld under German constitutional law.[111]

Determination of socioeconomic need by parliament or referendum would be a different question. Even then one would have to consider, under the German constitution, whether such determination violates basic individual rights that guarantee economic freedom and freedom of research. However, the mandate of the legislator is very broad. These questions were not discussed a length in our technology assessment. The main objection was that a legal test for socioeconomic need would replace market mechanisms with political decision making and ultimately lead to a planned economy.

Markets have become the decisive mechanisms in our society in determining whether a new technology or product is needed, and economic demand is normally taken as the irrefutable indicator of real need. The state may control the market to protect the moral order and minimise risk, but it may not try to "educate" market actors by deciding which economic demand constitutes a proper need and which does not. Whether video recorders, mountain bikes, industrial robots or holidays on the Mediterranean are superfluous (because we could live just as well or better without them) is not a legitimate state concern. Full political control over the need for a technology is confined to decisions on subsidising the technology or to cases where the state has a virtual monopoly on demand, such as for military or infrastructure technology. In line with this reasoning the political majority could still implement a preference for nonchemical weed control, but only through subsidies or tax incentives, not through a ban on the use of transgenic herbicide-resistant crops.

Most of the participants in our technology assessment defended the established institutional balance between markets and political decision making.[112] They pointed out that the decline of the socialist countries had demonstrated that no model for an efficient economy exists in which decisions on innovation and investment are the domain of politics. Moreover, whether the results were always convincing in those cases where the need for technology had actually been decided by the state may be a moot point: some examples are the Euro-fighter, the Transrapid monorail project, the use of nuclear energy and the continued use of subsidised coal burning for power generation.

The critics conceded the problems but insisted nevertheless that some revision of the institutional balance between market and politics was necessary, and that the question of whether we really need a new technology must be put on the political agenda. The controversy over this point remained unresolved in our technology assessment, as it has in the rest of the society. Opin-

[110] The Norwegian Ministry of the Environment was confronted with these problems when it had to decide on the release of Christmas begonia which had been engineered with antisense ACC-synthase to make the flowers more durable. The applicants referred to savings in chemical sprays normally used to make the flowers durable as the "benefit to the community"; they also mentioned export opportunities for Norwegian gardeners. The Department of Agriculture supported the argument of export opportunities. A dissenting opinion in the Norwegian Biotechnology Advisory Board denied any benefit; the flowers could be preserved without genetic modification or spraying if they were removed from warm rooms overnight. The competent authority finally granted the approval; it did not consider the export opportunities, but saw a "benefit to the community" in the gain of knowledge to be expected from the project and in the saving of chemical sprays (from the files of the Ministry of the Environment). The Austrian "social compatibility" clause has not yet been applied, see Martinsen (1997).

[111] Similar arguments apply to the broad mandate given the government in section 63 of the Austrian *Gene Technology Act* to restrict products if they imply an unjustified social burden. These are value decisions which must be left to the legislator (Waldhäusl, 1995).

[112] They opted instead for a regulation that genetically modified products be labelled so that consumers can choose (see section III E below). Labelling and consumer choice are, so to speak, the conformist response to the radical demand for a "fourth hurdle".

ions will depend among other things on how the gains and losses of modern technology are balanced. Those who see mainly losses will plead for the political control of needs in order to limit the dynamics of technology development; those who see mainly gains will reject such controls and defend the principle of freedom of innovation.[113]

E SPECIFIC PROBLEMS, RECOMMENDATIONS FOR REGULATIONS

In the course of our technology assessment recommendations were made on the regulation of various points. Most of these were controversial. Critics of transgenic herbicide-resistant crops had fundamental reservations, because they felt that the regulations implied acceptance of the technology, even with limitations. Advocates of the technology were worried that additional bureaucratic hurdles might be added on top of existing rules making the introduction and use of new technology practically impossible. Nevertheless, the disputing parties did establish some kind of lowest common denominator for various points. The critics were probably aware that a complete ban on transgenic herbicide-resistant crops was not a realistic political option. The supporters felt that some kind of additional regulation was the price to be paid in order to gain acceptance of such crops among the wider public.

Stricter regulations for genetically engineered plants were justified as precautionary safety measures that take the novelty of the technology into account and should be implemented for a limited period of time. Such regulations could be withdrawn subsequently if no problems arose; otherwise it would be necessary to consider whether these regulations should be extended to cover conventionally bred plants as well.[114]

[113] The question is by no means settled. While the exclusion of need criteria from administrative regulations may become common practice in almost all countries, it is not uncontested in the general public. The argument that decisions on whether ”we really need” biotechnological innovations should not be relegated to scientists, private investors and markets may well win the case through referenda—for instance, in Austria and Switzerland where the requisite initiatives have been taken; see Schweizer Bundesrat (1995).

[114] Some of the additional safety measures discussed here would not be merely possible but necessary conditions for the release of transgenic herbicide-resistant crops. Article 16 of the German *Genetic Engineering Act* rules that ”all safety measures must be adopted which are necessary according to the current state of science and technology”.

1 Testing for unexpected metabolic changes and food safety

The approval of nonselective herbicides implies routine testing to determine whether metabolites of the herbicide formed in transgenic herbicide-resistant crops could pose health risks for the consumer. Similar testing of other metabolic changes that occur in such crops, apart from herbicide metabolism, is or should be required in the law governing the introduction of genetically engineered plant varieties or food products. Tests should be designed particularly to control unintended or unexpected side-effects of the gene transfer and the transgenic gene product.[115]

Most participants in our technology assessment wanted to confine the testing to problems which are known to be characteristic for the species involved in the gene transfer. For instance, it should be controlled whether toxicants known to exist in the host plant species would be activated or increased (e.g. alkaloids in tomatoes or potatoes); this includes control of whether silent or cryptic metabolic pathways characteristic to the plant species are activated, that have the potential to synthesise toxicants. The tests should also ensure that toxicants or allergenic determinants characteristic of the donor species have not inadvertently been transferred to the host plant.[116]

[115] As a rule, food products from transgenic crops are subjected to stricter controls than products from conventionally bred crops. The latter do not have to be reviewed and approved prior to marketing, in most cases; how they test for the safety of their products, to avoid injunction or prosecution and damage claims under product liability law, is left to the producers. A shift to premarket controls in the case of transgenic food is common policy in all countries and in 1997 this policy was enacted in the Novel Food Regulation in Europe (EC 258/97). The US Food and Drug Administration considers a transgenic gene product that differs significantly in structure, function, or composition from substances found currently in food as a food additive that is not generally recognised as safe (GRAS) and, therefore, requires premarket review (1992). The FDA considers substances that occur unexpectedly in the food as a result of pleiotropic effects as ”added substances” which require formal premarket review if they occur at a level which may be injurious to health.

[116] The FDA (1992) includes toxicants, antinutrients and allergens in the list of potentially harmful constituents that must be tested if they are known to be present in the host or donor organism or related species. On the other hand, transgenic nucleic acids are not as such considered as potentially harmful; since nucleic acids occur in all cells they are ”generally recognised as safe”. In line with this argument the Administrative Court of Berlin ruled in 1995 that the mere presence of a ”foreign” nucleic acid does not yet constitute a ”harmful effect” on the legal

Even limited tests such as these go beyond what was hitherto required for the registration of new conventionally bred crop varieties. Metabolic changes were only tested in special cases where increased risk was indicated—for example, if the crops had been crossed with poisonous, nonedible wild relatives. Routine testing for alkaloid levels in potatoes was stopped in Germany some decades ago (although it applies in the US and has recently been reintroduced in Holland). That testing should be stricter for transgenic plant varieties met with opposition from some participants in the technology assessment. They argued that the risks of metabolic side-effects were exactly the same for conventionally bred plants and had been tolerated without testing. This had never led to identifiable problems. However, the point in designing additional tests for transgenic varieties is not so much that these varieties pose specific risks, but rather that they raise specific public concern. Whereas new conventional plants are easily accepted, transgenic plants are widely met with scepticism. This should be sufficient justification for special regulation.[117] For most of the proposed tests standardised protocols are available. Moreover, since transgenic varieties are still largely experimental in character, it can be assumed that a wide range of testing is being carried out in any case by the laboratories and companies that develop these varieties.[118] Therefore, to formally require additional testing is not likely to represent an undue burden.

Along these lines, it was recommended in our technology assessment that the substrate specificity of the transgenic gene product be tested if a metabolic function is transferred which is new in the recipient plant. Little or no substrate specificity indicates a higher probability that unexpected metabolic side-effects will occur. Tests could be carried out *in vitro* on substrates that have been selected according to biochemical theory. In addition, some *in vivo* testing could be carried out on selected model plants. Discussions in our technology assessment did not substantiate what the consequences would be if tests were to show that a transgene-coded product could change substrates; further metabolic testing of the transgenic plant would probably be appropriate in this case.[119]

Metabolic tests which control for known toxicants and allergens are available. However, tests which screen the complete plant metabolism for any unintentional or undesirable change induced by the gene transfer are technically not possible. The chances are low that unknown harmful constituents could be identified, which were never associated with the species involved in the transfer. Feeding studies with whole plants are not a feasible solution in many cases, because the test animals would die before they could be administered the (excessive) dose of plant material necessary to produce toxicological data. The postulate that metabolic testing should provide complete control of possible harmful side-effects, would indeed block any development of transgenic crops. If it were extended to conventional crops it would put an end to plant breeding in general.

Uncertainty about possible harmful side-effects that are unknown and untestable, are a normal problem of food safety. It is not possible to completely eliminate such uncertainty, either for conventionally bred or transgenic plants.[120] Therefore, it is questionable whether the fact

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goods protected by the German law, *Zeitschrift für Umweltrecht*, 3 (1996: 150).

[117] To that degree, the regulation should indeed be process-based, which means that formal review is triggered by the fact that the plant has been genetically engineered. This is the regulatory approach underlying the European directives. It does not imply that risk is assigned just because the plant has been genetically engineered.

[118] Extensive testing will be needed, in addition, to comply with the legal obligation to ensure that food products brought to the market are safe and wholesome.

[119] The FDA also gives no clear answer. With respect to intentional changes in biochemical pathways, it uses the formula that the metabolic effects on the host plant ”should be considered at the conceptual stage of development and monitored, when appropriate and feasible” (FDA, 1992). Substrate changes that testing has shown to occur can be viewed as analogous to intentional changes.

[120] This applies also to the question whether new proteins or new plants could themselves be (or contain) allergens. ”The FDA recognises that routine procedures for testing foods derived from new plant varieties for the presence of unknown allergens are not currently available. If the donor has no history of food use, the issue of allergenicity cannot be addressed at this time” (FDA, 1992). The problem is the same, if a nontransgenic plant variety with no history of food use is introduced. Whether in vitro digestibility assays are a valid method to exclude unknown allergens (see Astwood et al., 1996) remains to be seen. Monsanto used (among other indicators) an amino acid similarity analysis to known allergens for its assessment of the allergenic potential of the transgene product conferring glyphosate resistance to soybeans. ”The protein expressed was shown to be derived from a nonallergenic source, to have no significant amino acid homology to known allergens, to be rapidly degraded in a digestion model and to be present in low levels relative to common allergenic proteins. Most importantly, the introduced protein is closely related, both structurally and functionally, to the corresponding soybean protein. Based on this information, it was concluded, that this introduced protein posed no significant allergenic concern” (Fuchs 1995: 212).

that no tests exist to ensure complete control of such side-effects in the case of transgenic herbicide-resistant crops is sufficient reason to reject such crops.

2 Ecological testing and monitoring of genetically engineered crops

Environmental risk assessment has to consider case by case whether transgenic crop plants, or the respective transgenes, could possibly escape from cultivation and spread to natural habitats or wild species. Since the risk depends on the phenotype, the criteria for transgenic plants must be the same as those for nontransgenic plants. The following criteria were used in our technology assessment:

- the degree of domestication of the crop plant,
- the presence of related wild species with which the crop plant can crossbreed,
- the selective advantage that might be conferred by the transgenic trait, and
- the frequency of the release.[121]

On the basis of these criteria it was concluded that the herbicide-resistant crop plants considered in this technology are not likely to invade natural habitats and that the herbicide-resistance gene is not likely to proliferate in wild species (even if it would be captured occasionally as in the case of oilseed rape). The main reason was that herbicide resistance does not confer any selective advantage beyond the agricultural fields that are treated with the matching nonselective herbicide. It was nevertheless proposed that routine testing for increased fitness be included in the regulation of transgenic crop plants, even if the transgenic trait confers no selective advantage, since an unexpected increase in fitness could occur as a result of synergistic impacts or side-effects from the resistance-coding gene on the plant phenotype.

Tests usually performed in plant breeding are not designed to identify whether fitness in natural habitats has inadvertently changed. Test requirements for transgenic plants are more comprehensive at present. This seems to be justified. In many cases an investigation of fitness change will already have been included in the experiments carried out for developing new transgenic crop varieties. They should be embodied in the step-by-step procedures current regulations require for the release of transgenic organisms. While such testing seems indispensable if the transgenic traits confer a selective advantage outside agricultural areas, it may be reduced sooner or later in those cases where no selective advantage is to be expected, and perhaps it could be confined to highly competitive plants with a low degree of domestication (such as woody perennials). Highly domesticated annual or biennial crops are not likely to regain the ability to survive outside cultivation as a result of side-effects from gene transfer. Testing for increased fitness in transgenic crops is a precautionary measure which could, in principle, be dropped after a certain period of time, if experience shows that it is not necessary. But, it is also conceivable that experience would show that such testing is appropriate for transgenic plants in certain cases and that it should be extended to conventionally bred plants as well.

In our technology assessment, it was argued that the proposed testing could not, in fact, remove doubts about the ecological safety of transgenic plants. Testing will be performed on model plants at selected sites, and the results can only be extrapolated to other plants and locations to a very limited extent. It does not seem to be prudent, however, to set test requirements that cannot be met on the basis of our scientific knowledge at present. Predictions about the wider ecological effects of new crop plants remain uncertain—this applies to both transgenic and conventionally bred plants.

It was proposed in our technology assessment that the limits of ecological prediction and preventive testing be compensated by a more systematic postmarket monitoring of transgenic crops. If uncertainties about risks are inherent in new technology, and if these uncertainties must be accepted because otherwise all innovation would be blocked, then it seems good policy to ensure that harmful effects of the technology can be identified and regulated ”after the fact”. The monitoring of transgenic plants would have to be long-term, i.e. beyond the period required for field experiments under the law of genetic engineering.

Monitoring of transgenic plants would have to be coordinated with other monitoring activities, where these exist or are planned. Most participants in our technology assessment felt that proper ecological monitoring must be organised on a permanent basis through government institutions or agencies, and that it could not be delegated as research projects to universities. They referred here to the testing of fertilising schemes, that has been carried out continuously for more than 80 years by experimental agricultural stations in Germany. In the case of herbicide-resistant plants, this monitoring should cover not only the escape and uncontrolled

[121] These are standard criteria; see, for example, EPA (1994: 60512), ”Environmental Fate Analysis”.

spread of the crop and the transgene, but also the early recognition of the selection of herbicide-resistant weeds. It was further recommended that the long-term effects of nonselective herbicides on agrophytocoenosis and weed diversity should be monitored. However, there are pragmatic limits to any ecological monitoring. No programme can guarantee with certainty that all possible consequences will be discovered in time. This will not, as a rule, be an argument to forego as well the knowledge that could be gathered with reasonable effort. It was suggested that the ecological monitoring of transgenic plants should correspond in scope and method to the respective programmes carried out in the field of nature conservation.

Monitoring is not the answer for all ecological issues at state with transgenic herbicide-resistant crops. Specific programmes of safety research will be necessary, for instance, to clarify whether soil functions would be impaired by horizontal gene transfer from the transgenic crops. The importance of funding such research was emphasised in the technology assessment. It was further stressed that field trials with transgenic organisms should be designed and evaluated more often as ecological experiments, to ensure that these trials can really demonstrate a history of safe use of such organisms.[122]

3 Increasing the transparency of herbicide approvals

The approval of transgenic herbicide-resistant crops will remain a matter of controversy for the foreseeable future. Whether approval testing can provide sufficient safety is not, in the final analysis, a scientific question; it implies political decisions on the level of residual risk that can be imposed legitimately onto society. Under democratic rule such decisions have to be tolerated by those who disagree. It is therefore all the more important that the procedure for approval be as transparent as possible and that the reasoning behind decisions be explained to the public.

Criticism was directed against current practice in Germany for herbicide approval because of its lack of transparency. In particular, it was felt that the relevant toxicological and ecological dossiers should be made available not only to the competent authorities, but also to the public, so that they could, if necessary, be controlled and reproduced by independent scientists (for instance from universities). The point was not that the investigations should actually be repeated—this would, in many cases, amount to a waste of public money and, with respect animal testing, also violate existing law. However, it would increase transparency and trust in the procedure if, in principle, the investigations could be repeated.

It is unclear whether EC Directive 91/414 goes far enough in this respect. It allows access only to the summaries produced by the competent authority of the dossier provided by the applicants (test protocols that have to be applied are specified in the annex to the directive). Freedom of information concerning the complete dossiers is at odds with the commercial interests of the applicant, since competitors (second applicants) could then ”save” the costs of repeating the required investigations. On the other hand, one can ask if it makes sense to force second applicants to repeat all investigations. The legitimate interests of the first applicant could be protected without denying public access to relevant information, for example, by having second applicants contribute to the cost of approval, or by extending patent protection. With respect to animal testing, cost sharing with second applicants is already provided for in the law (for instance, article 13 of the German *Plant Protection Act*).

In order to increase transparency, it was also demanded in our technology assessment that reasons for refusing or withdrawing the approval for herbicides be disclosed. The public has a legitimate interest in and a right to be informed about the harmful effects or abuse of herbicides, which may constitute grounds for rejecting them or withdrawing the approval for their use.

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[122] The question of postmarket monitoring should not be confused with the question of whether the monitoring that (according to existing regulations) should be inherent in the step-by-step approach when releasing transgenic products is properly done. There is evidence that the field testing of transgenic plants has been inadequately designed and evaluated from the perspective of safety issues (see Wrubel et al., 1992; Mellon and Rissler, 1995; Rüdelsheim, 1995). Limited trials in small fields under conditions of reproductive containment cannot be conclusive evidence that large-scale commercial releases are harmless. Regal is more critical: ”Yet this sort of nondata on nonreleases has been cited in policy circles as though 500 true releases have now informed scientists that there are no legitimate scientific concerns” (1994: 11). But even if field trials are better designed and linked to safety research (see also Neemann and Braun, 1997) proceeding to commercial releases will nevertheless, in any case, remain a step beyond existing knowledge. Such steps must be based on the political assessment that one feels ”safe enough” to go ahead. Whether this assessment is correct should be controlled by postmarket monitoring. The competent authority in the United Kingdom explicitly requires the applicant ”to keep himself informed of any damage to the environment caused by the release or marketing [and] notify if there is any information which would indicate a change in the level of risk” (Deliberate Release Regulation).

4 Precautionary standards for herbicide certification: Zero contamination as goal?

There is probably general agreement that herbicide residues in food or elsewhere in the environment are undesirable. However, existing regulations permit certain levels of residues where it can be guaranteed that they will not be harmful for the consumer or the household of nature. Only in the cases of drinking water and groundwater are tolerance limits set to a level of zero contamination. Existing regulations for herbicide certification were criticised in the technology assessment from opposing perspectives. On the one hand, it was argued that consumer protection was inadequate because vulnerable groups (small children, the physically frail or sick) might still suffer harm from herbicide residues in food products. On the other hand, tolerance levels close to zero were considered as ”overregulation” and unjustified in toxicological terms. The discussions relativised both views.

Whether herbicide residues in foodstuffs represent a health risk depends not only on toxicity, but also on dosage. Most food plants contain natural substances which would have to be classified as toxicants (or mutagens or carcinogens) were they tested according to the standards of toxicology. The tolerance limits set for herbicide residues in food products are well below those levels which produce toxic effects (usually a hundredth of the so-called no-effect level). These limits are rarely exceeded; usually herbicide residues only amount to a fraction of what would be permissible; often they are below detection levels. Under these conditions, the call for zero contamination is hardly justifiable on the grounds of preventing human health risks. Zero contamination could perhaps be justified by consumer’s expectations that food products should satisfy certain standards of naturalness (absence of foreign substances). Such expectations, while undoubtedly legitimate, do not necessarily warrant additional regulation. Consumers might instead be advised to turn to markets of food products which meet particularly high standards of ”naturalness”, like organic farming products.

With respect to water protection standards, there was, first of all, consensus among the participants in our technology assessment that any discharge of herbicides into groundwater is highly problematic. Herbicides are an agricultural technology, and it would be reasonable policy therefore to try to confine the impacts of herbicides to the fields on which they are applied. Against this background, it was obviously not easy to argue for a relaxation of the zero contamination standard for groundwater.

The tolerance limits set for herbicide residues in drinking water by EC Directive 80/778 of 0.1 micrograms/litre for individual substances and 0.5 micrograms/litre in total are coming under pressure because, on the basis of normal toxicological criteria, they are some orders of magnitude below the limits necessary to protect public health. This is probably correct, but it may not be an objection. The extremely low tolerances (at the sensitivity limits of existing detection methods) have been set to ensure that water is measurably free of pesticides. Such regulation can be justified for reasons other than the protection of human health, namely, as a measure of food hygiene (since drinking water is a very special foodstuff), and as an incentive for better protection of groundwater, the most important source of drinking water in Germany. The objective to achieve zero groundwater contamination was accepted in the technology assessment; at least, there was no open dissent. No one advocated that the precautionary standards enacted in existing regulation be weakened; the need was rather to ensure their proper implementation.

5 Compliance with the conditions of herbicide approval, integrated crop protection, site-specific regulations

Opinions remained divided among the participants in our technology assessment whether stricter requirements should be set for the approval of herbicides in general, or nonselective herbicides in particular. This was no doubt due to the deep split of opinion over the question whether the agricultural use of pesticides is acceptable at all.

Apart from this controversy there was, however, some agreement that where the use of herbicides had caused obvious problems (e.g. groundwater contamination, selection of resistant weeds)´, the main reason was not inadequate regulation, but rather inadequate implementation of the regulation. Therefore, instead of adding further conditions for herbicide certification, the proper way to avoid problems resulting from lack of herbicide rotation, excessive applications or improper disposal of herbicides would probably be to improve monitoring of compliance with the regulations and to raise the standards for how farmers handle herbicides.

While the argument that nonselective herbicides are particularly likely to be abused because they do no damage to crops was rejected in the technology assessment, it was generally admitted that the application of herbicides often fails to meet the standards of ”good field practice” and the rules of integrated crop protection.[123] Therefore, the demand that compliance with existing rules be better monitored seemed plausible. On the other hand, it raises considerable problems at a pragmatic level. One can hardly imagine that the actual practice of farmers can be ”policed” comprehensively and effectively. To a large extent, one would have to rely on methods of counselling and education to improve compliance with the rule.

Moreover, it was pointed out that the standards of good field practice and integrated crop protection are fairly vague and, unless they are further specified, do not entail particularly clear guidance as to how herbicides should actually be applied practically on the farm. Consequently, the legal status of these standards remains ambivalent. The German *Plant Protection Act* imposes them as a goal, but implies no sanctions if they are violated.[124] However, the idea that the rules of good field practise be specified and enforced as legal regulation was also not welcomed by all the participants. The regulation of crop rotation sequences met with particular opposition, since this might force farmers to adopt cultivation systems that are not economical for them. Instead of encouraging the further bureaucratisation of agriculture, it would be better, on this view, to rely on proper counselling and education of farmers, and on the effects of good examples to demonstrate that integrated crop protection does in fact pay off in economic terms. Falling prices for agricultural products in the European Union provided sufficient incentives to reduce herbicide use and, therefore, no further regulation or additional incentives, such as a herbicide tax, would be needed. The principle of relying on economic constraints and market controls was rejected by other participants as completely unsatisfactory. The economic interest of farmers is clearly no justification for engaging in systems of crop husbandry that are not ecologically sustainable. Whether legal regulation of integrated crop protection was a viable alternative remained an open question in our discussions. It was generally admitted that, in view of the inevitable regional differentiation of farming practices, it would be very difficult to formulate plausible general rules.[125] Therefore, one would have to rely largely on proper counselling to specify the implications of integrated crop protection for local conditions.

Along these lines it was also suggested that herbicide use in particularly vulnerable areas—for example, where groundwater pollution is to be expected because of soil conditions—be regulated more often by negotiating the appropriate, site-specific precautionary measures with the farmer. It would also be much easier to monitor adherence to additional regulations if they were confined to restricted areas. This suggestion marks a break from conventional regulatory approaches and puts emphasis on more cooperative, persuasive policy instruments. Ever stricter conditions for herbicide approval and more bureaucratic control of all farming activities may not be the best way to improve the level of precaution. On the other hand, cooperative, site-specific arrangements will only be successful, if they are negotiated ”in the shadow of the law”, that is, if general regulations impose sufficiently strict tolerance limits to force something to be done in the area concerned.

6 Specific regulation for nonselective herbicides rotation

All participants in the technology assessment, even the advocates of transgenic herbicide-resistant crops, operated on the assumption that it is advisable to use nonselective herbicides only once in a crop rotation sequence and not with monocultures. The reasons given were that continuous use of nonselective herbicides would:

- select problem weeds, because all herbicides have gaps in their weed control spectra,
- increase the risk that herbicide-resistant weed populations spread,
- make the herbicide inapplicable for the control of volunteer crops from the previous vegetation period,
- have more serious environmental impacts,

[123] A number of participants have objected to the impression created in the discussions that the standards of good field practice were widely neglected in the use of herbicides. It is indeed true that the discussions focused on examples of such neglect and that no data were available to show how representative such examples might be. The point here is, however, that the situation is at any rate not different for nonselective than for selective herbicides.

[124] Article 6 ”Pesticides may only be used in accordance with good field practice. Good field practice implies that the principles of integrated crop protection are observed.”

[125] The amended German *Nature Conservation Act* (1997) exempts agriculture from the liabilities of nature conservation if the ”rules of environmentally friendly agriculture” are observed (article 2a). Accordingly, there is a need now to develop these rules into an explicit and standardized code (Bundestagsdrucksache 13/19930).

because a small number of herbicides would be applied over larger areas,

- lead to excessive elimination of weeds from agricultural habitats and to irreversible reductions in weed seed banks—a practice incompatible with the objectives of integrated crop protection,
- violate the rules of good field practice (especially in the case of monocultures).

Not all participants found all these arguments equally compelling, but it was agreed that there was sufficient reason to reject the use of one and the same nonselective herbicide without rotation. That resistant weed populations had to be prevented was probably considered as the most compelling reason for herbicide rotation.[126] Different views were held as to whether rotation of nonselective herbicides with different modes of action was advisable. While some participants pointed out that, in agronomic terms, this would be equivalent to the current situation in which all crops in a rotation sequence are treated with different selective herbicides (often used in combinations of tank mixtures), others insisted that weed elimination would still be more radical with nonselective herbicides. If the threat of genetic erosion of weed species is taken seriously and the principles of integrated crop protection strictly observed, one could probably argue that, even with rotation, nonselective herbicides should not be applied exclusively throughout the whole crop rotation sequence. The question was considered to be ”academic” for agriculture in Central Europe, since for cereal crops, an element in every crop rotation sequence, the use of herbicides is declining and the development of herbicide-resistant cultivars is apparently not being pursued.[127]

Should the restrictions to be observed for proper management of nonselective herbicides be legally regulated? This would not be necessary if bad management were purely a private matter and if farmers alone would have to bear the costs of the mistakes they made. But, this is not the case. Unnecessary or pointless herbicide applications are, by definition, incompatible with the legal objectives of integrated crop protection and therefore a matter of public concern. A regulation which specifies where and how often nonselective herbicides may be applied in the crop rotation sequence should be feasible in principle. There are examples of detailed regulations of this kind. For instance, in Germany atrazine (before being banned) could only be used in conjunction with one crop, namely, maize, only once in the vegetation period, with a maximum dose of one kilogram per hectare in postemergence treatment.

Whether such regulation could be established on a Europe-wide basis is an open question. A further issue is how compliance with the regulation could be monitored once herbicide-resistant cultivars and matching nonselective herbicides become readily available for all the crops farmers grow. Finally, it was argued that general regulations make no allowances for regional differences, but that local conditions have a crucial influence on whether and how rapidly nonselective herbicides can lead to problems. Proper site-specific choice of crop rotation sequence and herbicide management can perhaps be better ensured by counselling than by additional regulation. On the other hand, counselling may not be enough to exclude practices which, although disadvantageous in the long run, appear economically attractive for the farmer in the shorter run, as illustrated in the case of maize monoculture and the nonrotational use of atrazine.

7 Labelling of genetically engineered food

After lengthy discussions in the technology assessment all participants, including those from industry, agreed that genetically engineered food ought to be labelled as such. The rationale for labelling is consumer sovereignty, not protection of human health.[128] Health issues should be dealt with by testing for food safety before products from transgenic crop plants are placed on the market. Consumer sovereignty brings completely other aspects into play. While regulatory decisions about whether transgenic food products can be placed on the market must be based on accepted criteria and sound reasoning, decisions to buy such products or not can be based legitimately on individual (even idiosyncratic) motives, interests and preferences. Freedom of choice means that consumers can follow subjective fears, fundamental ethical reservations or

[126] It must be noted, however, that rotation while, a means to contain the problems that might result from herbicide-resistant weed populations, may not be a means to get rid of resistance in weeds again, since resistance will not necessarily imply a fitness penalty in absence of herbicide application (see Gliddon, IHE, 1994: 14).

[127] The situation may of course be different in other countries; weed grasses may have to be controlled in wheat by herbicides, and cross-resistance to wheat-selective herbicides is quickly developing. See Gressel (1996: 240).

[128] See also Rehbinder 1994: 99; health protection would be implied in the labelling, if transgenic food crops were ever approved that have been transformed with genes from a donor plant which is a known allergen.

political goals without asking whether their fears are well-founded, whether their ethical judgements are based on common sense or whether their political goals are supported by the majority. In order to guarantee freedom or choice, transgenic food products must be clearly labelled.

This principle was only reluctantly accepted in our technology assessment. It was argued that labelling would

- deceive customers by creating a false impression that the labelled products were dangerous,
- discriminate against genetic engineering, since other products of modern food technologies would not be labelled accordingly,
- be abused, or instance, to organise boycotts of transgenic food products for purely political reasons,
- be impractical if food products were processed further or mixed with other nontransgenic products.

The first three objections were found untenable; with respect to the fourth objection a pragmatic compromise was proposed. The very fact that food products from transgenic plants must be labelled might be misunderstood by a sceptical public or deliberately misinterpreted in political rhetoric as a signal of danger (". . . otherwise they wouldn't have put a label on it!"). This does not remove the rationale for labelling. Consumers have a right to be informed irrespective of whether they have a true understanding of genetic engineering or whether they realise that transgenic and nontransgenic foods are comparable in most respects. Prejudice and misinformation are surely factors of legitimate concern, but they can only be a reason for improving the level of information, but never a reason for withholding information.

A specific requirement that transgenic food products be labelled can hardly be considered discriminatory and unfair. The fact that genetic engineering has become an issue of public debate and source of anxiety should suffice to justify extra regulation. The same reasoning was also applied in the case of labelling food additives.

If transgenic food products have to be labelled, they can indeed more easily become the target of politically motivated consumer boycotts. Such boycotts are not in any way illegitimate or illegal, unless the declared goals are unconstitutional. In the past, consumers have used their freedom of choice to express opposition to apartheid in South Africa, to support Third World cooperatives, or to criticise the environmental behaviour of multinational companies. Why should they not be allowed to express their rejection of genetic engineering in their choice of foods! Thus, there is no reason to dispense with labelling requirement *because* it makes political boycotts possible.

On the other hand, it is doubtful whether labelling is required *in order to* make political boycotts possible. This view was propagated by some participants in our technology assessment. However, the sovereignty of the consumer is an economic right, not a political one. It is a fact that individuals may rely as much on political preference as on economic incentive when they "calculate" the usefulness of a product. They may, therefore, be really interested to learn whether the product comes from an automated factory or from labour-intensive production, what the company's policy is with respect to labour organisation or nondiscrimination of women, whether the firm is involved in the arms business or invests in low-wage countries, etc. Up to now, however, such information has not been required for product labelling. If consumers want this kind of information they must seek it from other sources. Obviously, it cannot be the purpose of product labelling to provide whatever information "politicised" consumers may want when they consider what to buy or not. But where do the limits lie?

The participants agreed that not only food consisting of or containing genetically engineered organisms should be labelled, but also food containing transgenes (and transgenic gene products). This would, for instance, apply to potatoes from herbicide-resistant potato cultivars. The same would apply if genetic engineering is used to remove or suppress a gene that normally occurs in the food. In this case the product is also "modified by genetic engineering", even though the modification may be indistinguishable from a natural deletion mutation. There was also consensus that products should be labelled even if they only contain substances (enzymes) from recombinant genes. One example is the use of rennin (chymosin) from genetically engineered bacteria for cheese making. Although such rennin may be indistinguishable from the one that has been extracted from calves, it nevertheless remains a "product of genetic engineering". Drugs must be similarly labelled, and there seems to be no grounds why this should not apply to foodstuffs as well. The need to be informed could, of course, disappear once it becomes generally known that all cheese is made with chymosin from genetically engineered bacteria.

There was no agreement about whether products should be labelled that contain neither transgenes nor their products, but that have been derived from transgenic crops. Sugar from herbicide-resistant sugar beet or oil from herbicide-resistant soybeans are examples. In these cases genetic modification leaves no trace in the final product; sugar and oil from transgenic crops are identical to sugar and oil from non-transgenic crops. Current labelling procedures provide only information about product properties in a narrow sense (the declaration of the country of origin is an exception in this respect), but not information on the mode of production if this does not affect the final product. Some participants argued, however, that in the case of genetic engineering the mode of production should also be labelled since the consumers may want to opt against the use of this technology in general.

It was pointed out that consumers could also exercise their sovereignty by choosing products which are explicitly declared to be *not derived from transgenic crops.* While it was not suggested that this option could replace labelling requirements altogether, it might be considered for those cases in which the use of genetic engineering in production has no effect on the product. Consumers who nevertheless wish to avoid such products would then have to turn to organic farming products or other alternatives. No consensus was reached on this point in the technology assessment. It seems, however, that both solutions are compatible with the recognised principle of consumer sovereignty; there is scope for political compromise here, which can be determined legitimately by majority decision.

It was admitted that labelling requirements involve pragmatic problems if they are extended to the entire processing chain of transgenic products. Would any food products containing flour or potatoes (or, according to the more radical proposals, even sugar) from transgenic crops also have to be labelled? What about mixtures of products from transgenic and non-transgenic crops? The critics of genetic engineering pleaded for maximum declaration of all secondary products. They denied that this would entail insurmountable practical problems, pointing to the German system of waste recycling labelled (the green dot) a vast number of products. Others felt that the pragmatic limits of labelling and compromises should be accepted. The idea of labelling will indeed be refuted if it is carried to the extreme. The larger the range of products labelled, the sooner it will become a normal expectation of the consumer that genetic engineering is somehow involved in food production; then one could do without labelling. Consumers who oppose such food would be forced to buy on alternative markets.

It may be true that widespread labelling requirements would be difficult to enforce in international trade. This does not mean, however, that we can dispense with an examination of whether such labelling is not in fact advisable in view of the manifest lack of public confidence in genetically engineered food in most countries.

F OUTLOOK: THE POLITICS OF TECHNOLOGICAL DEVELOPMENT

The discussions in our technology assessment showed that the participants had widely differing views about the direction in which society should develop and the role which modern technology can play. These differences cannot not be dealt with on the level of risk regulation, but they may help us to understand why risk regulation tends to polarise people and involve them in never-ending controversy. The differences can be summarised as follows.

1 Diverging views of the social role of technology

In our technology assessment, one side saw technology in modern society as an essential resource for solving problems. New technologies offer new opportunities, and the increase in opportunities must itself be considered a clear gain (provided the risks are under due control). From this point of view, the fact that transgenic herbicide-resistant crops play a pathfinder role, contributes to their usefulness. While they may not offer spectacular benefits by themselves, they help to break the ground for genetic engineering in agriculture and clear the way for other more important applications.

The other side, in contrast, did not see modern technology as part of the solution but as part of the problem. They emphasised that current environmental and social problems were in many ways attributable to the technological dynamics unleashed in our society, and that it was time to halt these dynamics. New high-tech opportunities will only continue the trends that have got us into the present mess. On this view transgenic herbicide-resistant crops were the initial step down a slippery slope. While they may be relatively harmless when viewed in isolation, they herald developments which will make our problems worse.

It is difficult to see how these divergent perspectives could be mediated. In our technology assessment it was at least possible to get rid of some of the clichés which abound in the public debate over these issues. Consensus was reached among the participants about the following points:

- Modern societies face ecological and social problems which cannot be overcome without structural reform. Even unambivalent supporters of modern technology did not claim that the world is in order or could be put in order by "business as usual".
- General goals such as sustainable development, fair distribution between North and South, and responsibility for future generations were not in dispute. The dispute referred to the strategies needed to reach these goals and the specific policies that could and should be adopted at present.
- No advocate of transgenic herbicide-resistant crop proceeded from the assumption that technological development would automatically lead to social progress, or that a technological fix could be found for every social problem. With respect to world food supply, for example, there was general agreement in the discussion that famine was at present primarily a problem of distribution, and that therefore the solution could not simply lie in new technology to increase production.
- On the other hand, opponents of transgenic herbicide-resistant crops did not blindly oppose all new technology. They accepted that new technologies might be needed to cope with existing problems. Thus it was clear that famine would again become a problem of production as the world population continued to grow, and that new technology would be needed to increase productivity—either in conventional or organic farming.

A key objection by the critics was that new technologies can never be judged in isolation, but must be viewed in the context of the social structures and ways of life in which they are embedded. It is indeed true that supporters tend to conceive of new technologies as a relatively neutral instruments which could be used for better or worse; they could be abused but, under suitable conditions, they could also help to solve our problems. In contrast, critics routinely deny that new technologies can ever be neutral in any way. New technologies are bound to have negative ecological and social effects under the existing social and economic regime because the conditions under which the technologies would really be useful simply cannot be established.

2 "High tech" as a lifestyle

The point that "high tech" is not so much an instrument but more a lifestyle which is part of the very fabric of industrialised societies was generally accepted by all participants. What was not accepted was the negative view of this lifestyle and the assumption that industrial societies are inherently unable to achieve reforms which would make the use of high technology ecologically and socially acceptable.

What is wrong with a lifestyle based on "high tech"? The pursuit of the domination of nature, for which genetic engineering represents a paradigm, cannot be the problem. As was pointed in the discussions, this pursuit is by no means unique to recent developments in technology. It is already a feature of traditional agricultural techniques and is just as much inherent in the alternative approaches of organic farming as in the most advanced strategies of genetic engineering. This argument was not discussed at length in the technology assessment, but it seems that integrated ecological management coordinating the biological feedback mechanisms that operate in natural systems, using breeding methods and mechanical agronomic techniques in order to obtain high yields and optimal control of environmental impacts, comes much closer to the Baconian ideal of the domination of nature than a method which simply transfers single genes from one organism to another.

It is to be expected that alternatives to current lifestyles will also be variations of a high-tech lifestyle. For example, an economy based on solar energy would hardly be possible without mobilising the entire repertoire of modern technology and further innovations. Therefore the objections to a modern high-tech lifestyle cannot be based on the degree of control we exert over natural processes, but only on the ends to which this control is put—which implicitly recognises the neutrality of technology. Does this mean that under different social conditions and with other goals for its application, genetic engineering would then also be acceptable for its critics?

The general assumption that new technologies will always have negative effects as long as they are embedded in industrial societies can hardly be defended, as evidenced by advances in medical technology and plant breeding techniques that have played a major role in feeding the world population. These are undisputed technological achievements of the industrial societies which one would not want to forego under any alternative social conditions. On the other hand, critics may still have a point in claiming that the dynamics of technological innovation in industrial societies tend to overload the environment, deplete natural resources and widen the gap between the world's haves and have-nots. It was not the purpose of our technology assessment to discuss basic issues such as what kind of production and economic regime we would need to protect the world's resources and ensure that available goods were divided more equitably, whether economic growth could be maintained much longer, or how industrial societies can function without growth. It is certain that opinions were as divided among the participants of the technology assessment as they are in the public debates pursued over these issues.

In the end basic political divisions among the participants remained unaltered in our technology assessment. The critics of genetic engineering felt that society would gain if it were possible to halt the further growth of the technology. They also claimed that organic farming represented a viable alternative to conventional agroindustrial techniques. The supporters of genetic engineering, on the other hand, were convinced that none of the obvious problems this society is facing could in any way be alleviated by suppressing the dynamics of technological innovation. Nor did they accept, as a rule, that organic farming was a better alternative for the environment in all respects or that it could provide the yields needed to ensure food supplies. Many participants were of the opinion that an ecologically sustainable agriculture of the future, that would ensure food supply for a growing world population, would have to be an improved version of the present system of high-tech agriculture, and that new technology, including genetic engineering, would be necessary to achieve this goal.

3 The compromise of technological pluralism

There seems to be no middle ground for mediating a dispute in which one side argues for more modern technology because it provides options to solve pressing problems, while the other side argues for less modern technology because it would only make the problems worse. We have incompatible political visions and strategies between which we must choose. Voting or referendum would suggest itself as a legitimate method to reach a decision in this case.

To a certain extent, it should be possible to have it both ways by combining some aspects of each conflicting view of the proper role of technology in modern agriculture. Society could, for instance, opt to introduce genetic engineering and, at the same time, provide additional support to improve organic farming methods. Occasionally it was argued in the technology assessment that technology policy should be based on a double strategy. Since no single technology can be expected to represent the ”best” solution to a problem for all times, it is advisable to ensure pluralism and avoid the emergence of technological monostructures in society. This would imply that alternatives to or variations of the dominant technology must at least be preserved, so that they can be resumed and further developed if the need arises in the future.

In the case of weed control, technological pluralism means that sufficiently large niches must be maintained for the use and innovation of mechanical methods, even if herbicides represent a superior technology according to received criteria. Going one step further, one recommendation was that organic farming as a whole should receive extensive support to develop it into a viable alternative, on the assumption that it is undesirable to be entirely dependent on chemically based agriculture as the only system of large-scale food production. In Central Europe a considerable increase of the area of organic farming could be achieved if subsidies were reallocated. This would create a ”laboratory” in which organic farming methods could be improved and evidence collected to determine whether organic farming could be developed into a realistic alternative to conventional farming, producing comparable yields at reasonable costs.

Such ideas were a concession to the advocates of organic farming, but required in return the admission that it is also legitimate to adopt new technologies, including genetic engineering (provided risks are properly controlled). Organic farming is thus regarded as an option in technology, not as a way of life. The discussion of these points was not brought to a conclusion in the technology assessment, and there was no opportunity to establish whether a consensus would have been reached.

4 The political function of participatory technology assessment

What was the political significance of our participatory procedure on transgenic herbicide-resistant crop plants? Can such procedures serve as a model for future technology assessment? Can it resolve conflicts over the acceptance of new technology? These questions were not discussed during the procedure itself; they are still under investigation at the Wissenschaftszentrum Berlin (WZB). A few remarks are given here.

1. A procedure of participatory technology assessment may be suitable to restore the credi-

bility of the experts. As an instrument of expert advice for policy making, it has probably less to offer. In our case the procedure just repeated and confirmed the knowledge that was available in the international discourse. It would probably have been possible to document this knowledge without a participatory procedure simply by commissioning reports from the respective experts. What would not have been achieved by such reports is the concurrent public demonstration of the credibility of experts. Credibility is an important and scarce resource in expert advice for policy making. It can be stabilised when experts are exposed to the critical questions and objections of ”counter-experts” in a symmetrical and fair participatory procedure.[129]

2. Argumentation is a medium for rationalising conflicts. While conflicts in public arenas are as a rule ”framed” as battles of arguments, the conflicting parties are mostly involved in the political mobilisation of the public rather than in the examination of arguments. A participatory technology assessment provides a social model of how the frame of argumentation can be taken seriously and how conflicting parties can be effectively committed to engage in true discourse. The procedure ensures that all relevant points will be brought together, that claims be substantiated and justified, and that objections be heard and answered. If there is any room to ”rationalise” political conflicts and explore the chances for consensus, it should become apparent under these conditions.

3. Participation is a political goal in itself. Experiments are being conducted in many modern societies with new participatory and cooperative forms of politics. To assess these experiments the question is not only whether they are necessary in order to resolve conflicts, but also whether they represent the kind of political culture one wants to promote in the society. Discursive models like the participatory technology assessment are superior (both in normative and functional terms) to ”one-sided” forms of participation like the right to be informed or to give comments, or to observe/testify in hearings. Inclusion in a discourse has a price, however, because it involves the conflicting parties in a process of argumentation which they cannot control and where they can never be sure that they will ”win” their case.

4. Conflicts over the acceptability of a new technology are not likely to be resolved in participatory procedures. Discursive technology assessments are social constellations of interaction which operate under ”ideal” conditions of symmetry, fairness and mutual respect. It is not to be expected that political conflicts that are fought in the public domain could be translated and transformed fully to the level of argumentation in such a procedure. Nor can one expect that the parties involved would really offer to relinquish their strategic interests in a process of argumentation. Acceptability conflicts are therefore not likely to be resolved in a participatory technology assessment; they will at best be redefined. Many of the rationalising effects of the procedure will only occur with those who observe the process of argumentation and not with the participants who actually pursue that process.[130]

5. Participation is not democratisation. Political disputes about new technologies will seldom be resolved by consensus. The real question is, therefore, how legitimate decisions can be taken despite the conflicting views. Participation in a technology assessment operates at a distance from the political decision. It is advice not decision making. Participation ensures the inclusion of a plurality of views in a process of political communication, but it is not a democratic transformation of political decision making. The participants do not need a democratic mandate, but they also do not have a democratic mandate. Whether participation will enhance the legitimacy of decision making and increase the willingness to accept majority votes remains an open question. It is a plausible assumption, however, that the refusal to grant participation will make it ever more difficult to arrive at legitimate decisions.[131]

6. Technology assessment may function as forum of constitutional debate. Conflicts over the acceptability of new technology often imply political demands which simply cannot be processed by the established procedures of decision making, such as the demand for political planning and democratic control of technological and social change. The political system must somehow ”return” such demands to the society. For that matter social forums of communication are needed which can deal convincingly with the interests, needs, hopes and fears reflected in such demands, even if they cannot translate them into effective regulation. Discursive technology assessment may be one example of such a forum, if it is extended into an organised discussion about how useful a new technology really is and what direction social develop-

[129] See van den Daele (1996).

[130] See Holzinger (1996).

[131] See van den Daele and Neidhardt (1996).

ment should take.

7. Participatory procedures cannot replace standard procedures of technology assessment. The participatory procedure initiated by the WZB was too costly in terms of time and money for all those involved to become incorporated in the routines of giving expert advice to political decision makers. The procedure would either have to be simplified drastically or confined to selected conflicts which are particularly significant.

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APPENDIX: Materialien zur Technikfolgenabschätzung

Heft 1: Einführung in das TA-Verfahren
W. van den Daele: Technikfolgenabschätzung als politisches Experiment
WZB discussion paper FS II 94-301

Heft 2: Risiken der physiologischen Veränderungen von transgenen Pflanzen
Gutachten: *P. Böger*: "Mögliche pflanzenphysiologische Veränderungen in herbizidresistenten und transgenen Pflanzen und durch den Kontakt mit Komplementärherbiziden"
Kommentar: *R.A. Weidhase*
WZB discussion paper FS II 94-302

Heft 3: Risiken eines horizontalen Gentransfers aus transgenen Pflanzen
Gutachten: *A. Pühler, I. Broer*: "Stabilität von HR-Genen in transgenen Pflanzen und ihr spontaner horizontaler Gentransfer auf andere Organismen"
Kommentar: *B. Tappeser*
WZB discussion paper FS II 94-303

Heft 4: Risiken der Verwilderung von transgenen Pflanzen
Gutachten: *H. Sukopp, U. Sukopp*: "Ökologische Langzeit-Effekte der Verwilderung von Kulturpflanzen"
Kommentar: *H. Scholz*
WZB discussion paper FS II 94-304

Heft 5: 'Evolutionäre Risiken' und die besondere Qualität gentechnischer Eingriffe: Kontextstörungen, Positionseffekte
Gutachten: *B. Weber*: "Evolutionsbiologische Argumente in der Risikodiskussion am Beispiel der transgenen herbizidresistenten Pflanzen"
Kommentargutachten: *A. Heyer, H. Saedler, L. Willmitzer*
WZB discussion paper FS II 94-305

Heft 6: Toxikologische Risiken der Rückstände von Komplementärherbiziden. Entwicklung der Aufwandmengen beim Herbizideinsatz
Gutachten: *H. Sandermann,K.-F. Ohnesorge*: "Nutzpflanzen mit künstlicher Herbizidresistenz: Verbessert sich die Rückstandssituation? Biochemische und toxikologische Aspekte"
Kommentar: *V. Haas, L. Peters*
WZB discussion paper FS II 94-306

Heft 7: Auswirkungen auf den Boden
Gutachten: *B.-M. Wilke*: "Verhalten der Komplementärherbizide im Boden"
Kommentar: *Ch. Siewert*
WZB discussion paper FS II 94-307

Heft 8: Probleme der Bodenerosion
Gutachten: *K. Auerswald*: "Auswirkungen des Anbaus von Kulturpflanzen mit gentechnisch erzeugter Herbizidresistenz auf das Ausmaß der Bodenerosion und der Pestizidabschwemmung"
Kommentar: *L. Ebner*
WZB discussion paper FS II 94-308

Heft 9: Auswirkungen der Komplementärherbizide auf Gewässer
Gutachten: *G. Klein*: "Auswirkungen der HR-Technik auf aquatische Ökosysteme"
Kommentar: *E. Dorn*
WZB discussion paper FS II 94-309

Heft 10: Auswirkungen der Komplementärherbizide auf Agrarökosysteme
Gutachten: *E.-G. Mahn*: "Zu den Auswirkungen der Einführung herbizidresistenter Kulturpflanzen auf Ökosysteme"
Kommentar: *M. Reschke*
WZB discussion paper FS II 94-310

Heft 11: Genetische Verarmung: Mögliche Auswirkungen des Einsatzes der HR-Technik auf die Vielfalt von Kulturpflanzen und der Ackerbegleitflora
Gutachten: *H. Umbach, J. Zeddies, R. von Broock*: "Auswirkungen der Herbizidresistenz-Technik auf die Züchtungspraxis und die genetischen Ressourcen"
Kommentar: *C. Freudling*
WZB discussion paper FS II 94-311

Heft 12: Pflanzenbauliche Veränderungen durch die HR-Technik.
Das Problem der Entwicklung resistenter Unkräuter
Gutachten: *K. Hurle*: "Mögliche Veränderungen in der landwirtschaftlichen Praxis durch die HR-Technik"
Kommentar: *P. Niemann*
WZB discussion paper FS II 94-312

Heft 13: HR-Technik und integrierter Pflanzenschutz
Gutachten: *R. Heitefuß, B. Gerowitt, H. Steinmann*: "HR-Technik und integrierter Pflanzenschutz"
Kommentar: *A. Gnekow-Metz*
WZB discussion paper FS II 94-313

Heft 14: Nicht-chemische Methoden der Unkrautbekämpfung
Gutachten: *H. Stöppler-Zimmer*: "Die nicht-chemische Regulierung des Wildpflanzenbesatzes im ökologischen Landbau als Alternative zum Herbizideinsatz"
Kommentar: *G. Bauer*
WZB discussion paper FS II 94-314

Heft 15: Betriebs- und volkswirtschaftliche Auswirkungen der HR-Technik
Gutachten: *V. Beusmann*: "Betriebs- und volkswirtschaftliche Auswirkungen des Einsatzes herbizidresistenter Nutzpflanzen (HR-Technik)"
Kommentar: *R.A.E. Müller*
WZB discussion paper FS II 94-315

Heft 16: Der Beitrag des Anbaus herbizidresistenter Kulturpflanzen für die Ernährungssicherung in der Dritten Welt
Gutachten: *S. Neubert,J. Knirsch*: "Der Beitrag des Anbaus herbizidresistenter Kulturpflanzen für die Ernährungssicherung in der Dritten Welt"
Kommentargutachten: *K. Leisinger*
WZB discussion paper FS II 94-316

Heft 17: Ethische Aspekte der gentechnischen Veränderung von Pflanzen
Gutachten: *G. Altner*: "Ethische Aspekte der gentechnischen Veränderung von Pflanzen"
Kommentar: *A. Stanger*
WZB discussion paper FS II 94-317

Heft 18: Bewertung und Regulierung der HR-Technik
I. Gutachten: *E. Rehbinder*: "Rechtsprobleme gentechnisch veränderter herbizidresistenter Pflanzen"; Kommentar: *J. Steinberger*
II. *W. van den Daele, A. Pühler, H. Sukopp, A. Bora, R. Döbert:* Bewertung und Regulierung von Kulturpflanzen mit gentechnisch erzeugter Herbizidresistenz (HR-Technik)
WZB discussion paper FS II 94-318